Chapter Four
Regulating Science: The Clinical Trial Controversy at the Regional Cancer Centre

1. Introduction

This chapter discusses the outbreak of and the subsequent negotiation over a dispute among the scientists at one of Kerala's most prestigious medical research institutions, the Regional Cancer Centre (RCC) at Thiruvananthapuram. RCC is the major cancer research and therapy centre in the state. The research projects as well as the functioning of the institute came under public scrutiny in the aftermath of a scientific controversy that appeared in the regional press in the month of July 2001. The controversy developed further into a crucial debate that raised serious concerns about the ethics of scientific research, scientific collaborations with research institutions in the West and patients' rights. The controversy also divulged the internal conflicts within a scientific institution and the ambiguities surrounding scientific research activity. The case also demonstrates certain important aspects of the science-media coupling and the stage-managing mechanism operative in the scientific public sphere.

In contrast with the other controversies discussed in the previous chapters, the preliminary site where the RCC clinical trial controversy originated was not the regional press. The eruption of the controversy in the scientific public sphere occurred late, and it can be seen that the rivalry between two groups of researchers within RCC predated the controversy. The issue that triggered off the controversy occurred between 12 November 1999 and 8 April 2000, when 25 oral cancer patients awaiting surgery were injected with chemical substances called tetra-O-methyl nor-dihydro-guaiaretic acid (M4N) and tetracycline nor-dihydro-guaiaretic acid (G4N) (Krishnakumar 2001). This clinical trial carried out at the RCC was part of an ongoing research in collaboration with Dr. Ru Chih C. Huang, faculty member of the Krieger School of Arts and Sciences of Johns Hopkins University (JHU) (ibid). The

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1 The RCC was established in the year 1981, and the institute is jointly sponsored by the central and the state governments. Several international agencies including the World Health Organisation (WHO), the International Agency for Research on Cancer (IARC) and the United Nations Population Fund (UNFPA) have acknowledged the institute as a centre of excellence. See, State Planning Board 2006.
clinical trial was administered by the research team headed by Dr. M. Krishnan Nair, the then director of the RCC.²

The controversy erupted when Dr. V.N. Bhattathiri, Associate Professor of Radiotherapy at the institute, filed a complaint regarding the clinical trial with the Human Rights Commission of Kerala on 18 March 2001 (ibid). The complaint “sought a detailed inquiry, appropriate action for the violations and preventive steps”, and said Dr. Krishnan Nair, who was the ‘principal investigator’, should be held responsible for the drug trials (ibid: 124). The complainant also contended that the clinical trials had been performed before the study was sanctioned by the Drug Controller General of India (DCGI) (ibid). Civil society organisations and a Malayalam television channel called Surya TV initially brought the issue to public attention. The TV channel’s prime time programme called ‘Aniyara’,³ which discusses issues of political and social concern with a flavour for investigative journalism, took up the issue and constantly followed it up.⁴ Slowly the issue developed into a public controversy and the regional press became the major site for debate and deliberation. Although it remained unacknowledged by most of the regional newspapers, the role of Surya TV was crucial in exposing the issue.

2. Drawing the Battle Lines

The issue was first reported in the regional press in the month of July 2001 when a petition was submitted to the Chief Minister of Kerala,⁵ demanding a proper enquiry into the corruption and other ‘disorders’ in the RCC and a news report on the petitioning appeared in the Madhyamam.⁶ It was reported that the chemicals involved in the clinical trial had already been banned in many of the developed countries. The RCC had injected a chemical substance that catalysed cancerous growth in patients

² The research team had Dr. Manoj Pandey and Dr. Radhakrishna Pillai as co-researchers. See Krishnakumar 2001.
³ ‘Aniyara’ literally means ‘backstage’. The programme was directed and anchored by Alias John, a reputed social activist-turned-TV journalist and produced by his own company called ‘National Television’ (NTV).
⁴ Many of the speakers interviewed by me pointed out the role of the Surya TV in exposing the issue. Later on it was alleged that the TV channel had deliberately been trying to defame the RCC, and was hands-in-glove with the Adayar Cancer Institute, Tamil Nadu, though the allegation did not get much currency in the scientific public sphere. Personal interview with Dr. Joy Elamon, 24.04.2006 and Dr. C.R. Soman, 26.04.2006.
⁵ A previously unheard-of organisation called the All India Medical Service Centre (AIMSC) was the petitioner. The name of the organisation appeared only in this particular news report. The CM of Kerala is the chairperson of the RCC governing body, and hence the petition was submitted to him.
without their consent and exported the malignant tissue collected from patients to the JHU for further research—it was argued in the petition.\(^7\) The petitioning was not reported in other newspapers, but *Surya TV*’s reporting of the clinical trial issue invited wide public attention. The *Madhyamam* reported the demonstration organised by the Thiruvananthapuram district committee of the Youth Congress in front of the RCC, demanding a vigilance enquiry into the clinical trials.\(^8\) Other newspapers maintained their silence, indicating that the battle lines were fixed well in advance, before the issue entered the scientific public sphere: Dr. V.N. Bhattathiri, the *Surya TV* and the *Madhyamam* where on one side and the director, Dr. Krishnan Nair and the other newspapers on the other side.\(^9\)

The divide became more noticeable in the following days. The *Madhyamam* attempted to expose the ongoing conflict within the RCC over the corrupt practices of its director and his allies. The newspaper referred to the verdict of the Kerala High Court on a petition filed by Dr. V.N. Bhattathiri regarding his removal from the chairpersonship of the Head and Neck Clinic.\(^10\) The petition was filed in the wake of a major administrative reform in the RCC, when new speciality clinics were inaugurated in the institute. Interestingly, it was only *Malayala Manorama* and *Kerala Kaumudi*—the two main dailies which backed the RCC director throughout the deliberations—which reported the administrative reforms in the institute and the reports were highly appreciative of the reforms.\(^11\) The High Court urged the RCC to settle the seniority dispute amicably within the institute.\(^12\) After the High Court’s verdict on the issue, the Citizen’s Protection Forum of Thiruvananthapuram filed a

\(^7\) Ibid.
\(^9\) *Kerala Kaumudi* and *Malayala Manorama* openly defended the RCC director throughout the controversy as will be discussed. The *Mathrubhumi* did not explicitly support any of the coalitions, but a majority of its news reports represented the pro-RCC actors in the scientific public sphere. The *Deshabhimani* took a non-partisan view on the matter, but critiqued the governmental interventions especially in the final phase of the controversy. In my personal interview with a reputed media analyst and journalist from Kerala (name withheld), it was pointed out that many of the newspaper authorities had nice and cordial relationship with the RCC administration and especially with Dr. Krishnan Nair. If the newspaper owners or the reputed journalists recommended a patient, he/she was given great priority and utmost care in the RCC. In return the newspapers always helped the institute maintain good public relation by publishing reports whenever needed. He also pointed out that the chief editor of one of the major newspapers was a member of the governing council of the institute.
\(^10\) Ibid.
\(^11\) Each speciality clinic was meant for the treatment of the cancer that affects a specific part of the body. A speciality clinic consists of a team of experts led by a senior doctor. See “RCCyil Speciality Clinikkukal Erppeduthi”, *MM*, 08.07.2001, p.4; “RCCyil Speciality Clinikkukal”, *KK*, 08.07.2001, p.10.
\(^12\) “RCCku Munpil Dharma Nadathi”, *M*, 13.07.2001, p.3.
Public Interest Litigation (PIL), questioning the administrative reforms that denied the right of the patients to consult the doctor of their preference, and questioned the director’s right to regularise temporary appointments. The PIL also demanded the cancellation of the recent extension of the tenure of the director. The allegations clearly show that the conflict within the institution was multifaceted and with a long history, finally erupting out into the public as a controversy over the clinical trials.

All the newspapers other than the Madhyamam continued ignoring the issue even at this stage of high newsworthiness. The Madhyamam continued with its exposition of the malpractices in the institute. The newspaper reported the ban of the research projects of the School of Medicine of the JHU by the US government, emphasising the ethical violations involved in the clinical trials undertaken by RCC for the JHU. This ban by the US government was enforced following the death of Ellen Roche, a healthy woman who was a volunteer for the clinical trial of a drug used to treat asthma, allegedly due to the injection of an experimental drug. The US government withdrew all federal funding to the School of Medicine of the university and criticised the researchers for not informing the volunteers about the possible side effects of the drug. The news report thus suggested the inhuman nature of the medical research being carried out in the JHU and made public the research collaboration between the university and the RCC.

These preliminary interventions of different actors that included a scientist, a television channel, a newspaper and a few civil society organisations were successful in mobilising the scientific public sphere, where the controversy snowballed through rigorous negotiations, enrolling in the process a wide range of actors. The RCC administration that had thus far been silent was now forced to speak, and it responded to the allegations through the newspapers. The Kerala Kaumudi reported the RCC administration’s ardent denial of the allegations pointing out that it was not NDGA (Nor-dihydro-guairetic acid) that had been banned by the Food and Drug

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13 Ibid.
14 Ibid.
15 The one and only exception was a small news report in the local edition of Kerala Kaumudi about the PIL filed by the Citizens’ Forum. See “RCC Directorude Kalaavadh Neeitiyathinu Ethiraya Harjiyil Notice”, KK, 25.07.2001, p.3.
17 The drug was ‘Hexamethonium’ used in combination with sodium bicarbonate, which was not scientifically allowed, according to the Madhyamam report. See ibid.
18 Ibid.
Administration (FDA) in the USA that was administered, but M4N, a derivative of the NDGA which was neither fatal nor banned. It was also stated in the news report that M4N was found to be completely secure in the first phase of the experiment in different countries including the USA. The RCC further claimed that its ethical committee had approved the clinical trial and consent had been obtained from all the twenty-five patients who were administrated the drug. The argument was further supported when Dr. Krishnan Nair, the director of the RCC and the scientist who was responsible for the clinical trial, released a press note defending the experiment, and it appeared in the Malayala Manorama. Dr. Krishnan Nair reiterated that the drug used for the clinical trial was not a banned one and that it did not have serious side effects, but had a positive impact on the majority of patients. It was also claimed that the sixteen patients to whom the drug was administrated were cured and five patients responded positively, and only one patient showed the development of a secondary tumour. Responding to an allegation that two patients who had been subjected to the clinical trial died, the director suggested that the drug was not the cause of death, but medical complications such as diabetes were to be held responsible. Dr. Krishnan Nair said that Dr. Ru Chih C. Huang and her team would arrive on 2 August and conduct a press conference explaining the research project to the media.

3. Governmental Interventions

The dispute entered a new phase in the following days when A.K. Antony, the then Chief Minister of Kerala entered the scenario. All the five newspapers began reporting the issue from this point. The CM declared that his government was highly concerned about the unfortunate developments and would enquire into the charges of the malpractices in the RCC, though utmost care would be taken to safeguard the

19 "Nirodhicha Marunnu Kuththivechittilla: RCC", KK, 15.07.2001, p.10. The news report was quoting an explanatory note by the RCC administration to the health minister of the state.
20 Ibid.
22 Ibid.
23 Note the confusion regarding the number of patients. According to the news report in Kerala Kaumudi the number was 25, and in the report by Malayala Manorama the number was reduced to 16.
24 Ibid.
25 The source of the allegation is not clear. As we are going to see, the same allegation reappeared in the scientific public sphere at a later phase.
26 Ibid. However, it was not discussed if the diabetes could have been drug-induced.
27 Ibid.
credibility of the institute.\textsuperscript{28} The CM also hinted that punitive measures would follow if the allegations were confirmed.\textsuperscript{29} The central government was also reported to be concerned about the issue.\textsuperscript{30}

Such statements from the government had a very strong impact on the debate. In the consecutive days, the RCC administration became very vocal in their denial of the allegations. It was reiterated that the drug used in the RCC was the harmless M4N\textsuperscript{31} and not NDGA, the banned one.\textsuperscript{32} It was explained that these were two different chemicals and unlike the latter, M4N did not dissolve in water and thereby did not affect other organs.\textsuperscript{33} The tumours were removed from the patients seventy-two hours after the drug was injected in order to conduct pathological tests, the administration explained.\textsuperscript{34} The RCC emphasised the transparency of the clinical trials when they contended that the patients were informed about the experiment a priori and that a letter of consent was signed by all the patients and their relatives.\textsuperscript{35} The RCC also pointed out that the treatment was provided free-of-coast for the patients, adding a humanitarian and ethical dimension to the clinical trials.\textsuperscript{36} Such research projects had to be undertaken by the RCC, since it was part of its mandate as a leading cancer research institute, the public was told.\textsuperscript{37} It was clarified that the antiviral agent developed by the JHU was also undergoing clinical trials in South Korea.\textsuperscript{38}

In India, the institute revealed, the ethical committees of the Banaras Hindu
University (BHU) as well as the J.K. Cancer Institute at Kanpur had agreed to collaborate with the research project of the JHU.\textsuperscript{39} A similar study of the impact of the drug on skin cancer was to be undertaken in Singapore, the RCC pointed out.\textsuperscript{40} Such references were used to reassure the public of the acceptance of the clinical trial in other contexts, and thereby arrest the erosion of public trust in the institution as well as to regain the credibility of the RCC clinical trials.

Interestingly enough, the RCC warned that any public criticism of scientific research would affect the progress of the institute as well as the trust of the patients admitted to the institute.\textsuperscript{41} It was pointed out that such negative criticism would discourage international research institutions and multinational drug companies from entering into research collaboration with the institute.\textsuperscript{42} The endeavour of the RCC administration to defend the institution was strongly supported by the RCC Employees' Association, when it demanded an immediate scrapping of the public debate on the issue.\textsuperscript{43} The Employees' Association pointed out that any public debate on the issue would only taint the reputation of the RCC, and hence insisted on an immediate withdrawal of all the parties from the controversy.\textsuperscript{44}

The RCC director called for a press conference\textsuperscript{45} in which he reiterated the earlier arguments, but ostensibly divulged more details about the research project. He claimed that the experiment had been continuing at the RCC since 1998, and the patients were chosen for clinical trials with the permission of respective doctors.\textsuperscript{46}

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\item\textsuperscript{39} Ibid. See also “Nirodhicha Marunnukal RCCyil Upayogichilla: Director”, \textit{D}, 29.07.2001, p.4.
\item\textsuperscript{40} “Gaveshana Sthapanam Ayathinal Marunnu Pareekshiche Theeroo: Cancer Centre”, \textit{M}, 28.07.2001, p.5.
\item\textsuperscript{41} Ibid.
\item\textsuperscript{42} Ibid.
\item\textsuperscript{44} “RCCyude Salpperinu Kalankam Undakkaruthu”, \textit{KK}, 27.07.2001, p.3.
\item\textsuperscript{45} The press conference itself was controversial, as it had been postponed to the next day at the last moment without prior notice. According to the \textit{Madhyamam}, the public relations officer of the RCC explained to the journalists present at the press conference on Friday, 27 July 2001 that the press conference was postponed to the next day and then distributed a press note, instead of answering the questions raised by the journalists regarding the controversy. The newspaper reported that the journalists protested and then the PRO explained that the press conference was postponed to make ensure the presence of the representatives of the JHU. See “RCCyude Pathra Sammelanam Vivadamayi”, \textit{M}, 28.07.2001, p.5. See chapter 5 for a discussion on the role of press conference as a deliberative space and source of information.
\item\textsuperscript{46} “Marunnu Pareekshhanam Nadanathu Niyama Vidheyamayi: Dr. Krishnan Nair”, \textit{MB}, 29.07.2001, p.5; “Nirodhicha Marunnukal RCCyil Upayogichilla: Director”, \textit{D}, 29.07.2001, p.4.
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project had been initiated. He also stated that the drug (M4N) was a derivative of the NDGA developed by the JHU. The drug was proven harmless and effective in experiments conducted on 36 mice. The JHU, the journalists were told, then approached the RCC for undertaking clinical trials on human beings. The RCC was approached by the university because the drug was targeted on oral cancer, which was very common in India. Furthermore, the RCC received Rs. 25 lakhs per year for the clinical trials, the director said. He also clarified that the RCC and the JHU would equally share the royalty of the patented drug as collaborators in the project.

Nevertheless, he offered to enquire into the allegation that another chemical substance called G4N was experimented with at the RCC though the ethical committee of the institute had granted clearance solely for the trials of M4N. Dr. Krishnan Nair agreed that the approval from the DCGI had not been received even though the RCC had applied for the same in September 1999.

A few days later, the regional press reported that an enquiry had been ordered by Dr. C.P. Thakur, the then health minister of the Government of India. The minister emphasised that enquiry would also look into whether M4N had been banned in the USA. The State Government in turn appointed a single-member enquiry

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47 Ibid.
52 “Marunnu Pareekshichathu Ethical Committeeyude Anuvadathode: RCC Director”, MM, 29.07.2001, p.7. However, the report in Deshabhimani contradicted this. The report quoted Dr. Krishnan Nair as saying that the RCC clinical trial had been approved by both the RCC ethical committee and the DCGI. See “Nirodhicha Marunnukal RCCyil Upayogichilla: Director”, D, 29.07.2001, p.4. The press note of the Health Ministry of the GOI which was widely reported in the regional press later on said that the DCGI had approved the import of M4N from the JHU in February 2001. See “RCCyile Nirodhitha Marunnu Prayogam Kendram Anweshikkunnu”, MM, 31.07.2001, p.9; “Nirodhicha Marunnu Upayogichathu Anweshikkum”, D, 31.07.2001, p.1. It was also mentioned that the approval was granted on the basis of the recommendations of the RCC ethical committee. See “RCC Marunnu Pareekshanam Kendram Anweshikkunnu”, KK, 31.07.2001, p.1.
committee (the Parikh Commission) to probe into the clinical trial controversy. The Human Rights Commission of Kerala accepted the complaint filed by Dr. Bhattathiri and summoned the RCC director to appear before it since the RCC failed to submit an explanatory report on the clinical trials as demanded by the Commission. In its editorial, the Mathrubhumi raised the legal and ethical issues associated with the controversy and demanded a judicial inquiry into the matter.

The intervention of the state government was, however, not wholeheartedly welcomed by the rival coalition. Dr. Bhattathiri criticised the state government for trivialising the issues he had raised by appointing Dr. Parvesh Parikh who was a junior doctor as the single-member enquiry commission. Bhattathiri demanded that a committee consisting of medical and legal experts and social activists in lieu of the Parikh Commission be instituted to carry out a proper investigation into the dispute. Following Dr. Bhattathiri, the Madhyamam criticised the creation of a single-member commission, pinpointing the allegation that the objective of the commission was to safeguard the RCC director who was quite influential at the governmental level. The newspaper also pointed out that Dr. Krishnan Nair and Dr. Parvesh Parikh were friends and that they had even co-authored a research paper. Thus, rival actors were trying hard to expose the tacit nexus between the state government and the RCC administration. They strongly opposed such a move from the government to rescue the RCC and its researchers.

4. Strengthening Coalitions

The entry of governmental regulatory bodies stirred up negotiations in the scientific public sphere, offering space to new actors, thereby expanding the scope of the debate. The intensification of the deliberations in the scientific public sphere in the

55 Dr. Parvesh Parikh who was appointed as the single-member enquiry commission was Professor of medical oncology in the Tata Memorial Hospital, Mumbai, and also the secretary of the Indian Cooperative Oncology Network (ICON). “Dr Parikh Anweshikkum”, MB, 01.08.2001, p.1; “Cancer Centre Vivadam: Anweshikkan Utharavu”, D, 01.08.2001, p.10; “Dr Parikh Anweshikkum”, M, 01.08.2001, p.1; “RCC Vivadam Anweshikkan Ekanga Commission”, KK, 01.08.2001, p.1.
57 “Cancer Centre: Judicial Anweshanam Venam”, MB, 01.08.2001, p.4.
59 Ibid.
60 “Cancer Centre: Anweshanam Nishpakshamakillennu”, M, 02.08.2001, p.5.
61 Ibid.
consecutive days occurred in tandem with the diversification of the coalitions in favour of and against the clinical trials at the RCC. This phase witnessed more actors entering the deliberative phase, and a wide spectrum of issues was debated in the context of the controversy. The newspapers continued to be allies in the respective coalitions, but they began to report the opponents' arguments more openly, stripping down the veil of silence. The deliberations in the following days indicated that the rival coalitions were gradually acquiring legitimacy and acceptance in the scientific public sphere. This was catalysed by the JHU’s entry into the scientific public sphere. The university published a disclaimer on its website denying any association with the clinical trials undertaken by the RCC. This denial was widely reported in the regional press. They highlighted the point that no financial assistance was offered by the university to the research project undertaken by RCC, and that it had asked Dr. Ru Chih C. Huang to withhold the research. The JHU, in turn, constituted an enquiry committee to probe into the allegations and stated that punitive action would be taken if the protocols and code of conduct of the university were breached by its faculty member. This act from the side of the JHU tarnished the high public support and trust enjoyed by the RCC and its researchers. The deterioration of public trust in the RCC and the gradual public recognition of the rival scientists’ arguments at this stage led to a diversification of the subjects debated and also the expansion of the scope of the controversy.

4.1. The Public Scrutiny of Medical Research

The ethical and political aspects of the medical research were a crucial concern in the scientific public sphere at this juncture. The Malayala Manorama on its editorial page presented the arguments of the RCC director and the counter arguments of Dr. C.R. Soman, a public health expert. In the article, Dr. Krishnan Nair contended that the controversy was part of an ongoing slander campaign against

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63 Ibid.
65 Ibid.
66 Dr. C.R. Soman was formerly a Professor and the Head of the Department of Nutrition at the Medical College, Thiruvananthapuram. Currently, he is the director of the Health Action by People, an action-research NGO in Thiruvananthapuram.
him and the RCC. On the contrary, Dr. Soman pointed out that M4N was not radically different from the banned drug, as the former was a tetra-methyl derivative of NDGA, the basic molecule. He also argued that G4N which had been used in the clinical trials along with M4N was a tetra-glycinal derivative of NDGA. Further, he disclosed that the primary objective of research was to test whether these chemicals would decelerate the growth of the Human Immuno Virus (HIV) and later it was tested specifically in the treatment of oral cancer, and to study its impact on the growth rate of the Human Papillomavirus (HPV). Dr. Soman alleged that the protocol for medical research was not followed by the JHU and the RCC as the chemical was directly administered to human beings after experiments had been conducted on mice. The drug under trial was injected into cancer patients who were not in a critical stage, he argued. He pointed out that this was against the medical research ethics which allows such dangerous clinical trials only on chronic patients to whom all available treatment had been exhausted. Dr. Soman contended that it was not possible to say that the chemicals did not cause any side effects, because it was for the first time that clinical trials were being performed anywhere. The argument that the RCC ethical committee had approved the clinical trial was preposterous, Dr. Soman pointed out, since the RCC director himself was the chairperson of the committee. He also alleged that a new drug company was registered in Singapore to manufacture the drug, if the research was successful. He also turned down the claim that the RCC would get any royalty, pointing out that the JHU exclusively owned the patent for the drug. Based on these arguments, Dr. Soman emphasised the unethical and unlawful nature of the RCC clinical trials.

The editorial page article in the Malayala Manorama was trying to present the pros and cons of the controversy by providing space for the RCC director and Dr. Soman under the guise of ‘media neutrality’, despite the newspaper’s open defence of the RCC. This indicates that the even though a powerful ally of the RCC in the controversy, the newspaper was forced to enter into a dialogue at this stage,
relinquishing its early strategy of suppressing the dissenting actors. The entry of Dr. Soman as a powerful associate made the rival coalition more powerful and Dr. Soman became the main protagonist of the rival coalition.

The internal ambiguities of medical research turned to be the focus of discussion as the controversy unfolded in the following days. Two public discussions on the controversy organised by the Forum for Patients' Rights (FPR) and the Indian Medical Association (IMA) were widely reported in the regional press, influencing further the course of negotiations in the scientific public sphere. In the debate on 2 August 2001 at Thiruvananthapuram organised by the FPR, a strong opponent of the clinical trials, the prevalence of similar unethical research practices in different parts of the country was noted. The forum demanded a judicial enquiry into the issue. Advocate Vincent Panikkulangara, who was an activist of the Forum, pointed out that a 'chemical substance' and not a 'drug' was injected into the patients and explained that a chemical substance under clinical trial attains the status of 'drug' only after getting the approval of the DCGI. He opined that a doctor did not have the right to prescribe a chemical substance masquerading as a drug to a patient. Dr. V.N. Bhattathiri argued that the Parikh Commission was simply a charade established to rescue the culprits. He also denied the charge that his expose of the issue to the public would damage the institution since such a move was inevitable to safeguard public interest. At the meeting, Dr. Gangadharan, another member of the rival group of RCC scientists, described how the drug undergoing clinical trials was administered to Mr. Gopal, a patient from Tamil Nadu, without the consent of his doctor. The procedural lapses in the RCC-JHU research amounted to human right violations. In general, it was concluded at the meeting that the clinical trials were proof of the unethical practices and human right violations prevalent in the field of medical

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75 The Forum for Patients' Rights is a civil society organisation which took a strong anti-clinical trial position in the controversy.
77 “RCCyl Judicial Anweshanam Venam”, MB, 02.08.2001, p.3.
79 Ibid.
82 Ibid. Gopal was Dr. Gangadharan’s patient at the RCC.
science research. The FPR seminar thus led to the consolidation of the voices of the opponents of the RCC clinical trial.

This spirit was consolidated by the ‘open debate’ organised by the IMA, on 3 August 2001, titled “Drug Trials: Right and Wrong”.84 While the FPR seminar accorded space exclusively to the opponents of the clinical trial, the IMA seminar was inclusive in terms of participation. Therefore, the regional press accorded the seminar wider coverage. However, the seminar ended up in pandemonium followed by a heated argument between the rival groups. Two major points were emphasised at the seminar: firstly, the question of ethics in medical research, and secondly, the rival scientists’ act of bringing the dispute to the public. The forum resolved that transparent guidelines had to be developed for medical research.85 The seminar also expressed its concern over the erosion of public trust in the RCC.86

The erosion of public trust in the RCC that was simultaneously a research institute and a super-speciality hospital had been raised by several actors. A.K. Antony, the then Chief Minister of Kerala shared the view that there had been an erosion of public trust in the RCC. The CM requested the rival groups of scientists as well as the media to abstain from any act that might damage the reputation of the RCC.87 He pointed out that the RCC was an institution that acquired its fame as a result of years of painstaking hard work.88 He cautioned the scientists against any attempt to take the issue to the street as it would end up in the collapse of the institute.89 He also pointed out that the state government, the central government, the Human Rights Commission and the High Court had been investigating the issue and therefore a public, ‘political debate’ on the issue was unnecessary.90 And it was more

85 “RCC Vivadam: Doctormar Thammil Tharkkam”, M, 04.08.2001
86 Ibid.
87 “RCCkkethireyulla Pracharanathil Ninnu Pinmaranam: Mukhyamanthri”, MB, 03.08.2001, p.2; “RCCye Nasippikkaruthu: Mukhyamanthri”, KK, 03.08.2001, p.3.
88 “RCCye Nasippikkaruthu: Mukhyamanthri”, KK, 03.08.2001, p.3.
89 “RCCkkeithireylla Pracharanathil Ninnu Pinmaranam: Mukhyamanthri”, MB, 03.08.2001, p.2; “RCCye Nasippikkaruthu: Mukhyamanthri”, KK, 03.08.2001, p.3.
90 Ibid.
or less mandated by him that any destructive move against the institute would be regarded as a serious public offence.\textsuperscript{91}

This pro-RCC statement by the CM did not go unopposed in the scientific public sphere. M.N. Vijayan, a renowned Marxist intellectual of Kerala wrote an editorial in the \textit{Deshabhiman} magazine,\textsuperscript{92} and was quoted in the regional press. He pointed out that the CM’s statement was justifying unscientific and inhuman research in the RCC and went against the democratic spirit.\textsuperscript{93} He emphasised the need for democratisation of medical research while arguing that the patients’ consent was imperative for the conduct of such experiments on their bodies.\textsuperscript{94} He also denied RCC the possibility of immunity from public scrutiny.\textsuperscript{95} In a statement issued by the EMS Cultural Forum, the opinion of the CM was criticised for its defence of Dr. Krishnan Nair and the unethical clinical trial conducted at the RCC.\textsuperscript{96}

However, the pro-RCC coalition gradually recuperated from the lethargy of loss of public trust by forming a strong defence of the institution with the enrolment of more actors. The CM’s open defence of the RCC was a great motivation for the supporters of the RCC and a great hue and cry was raised in the scientific public sphere against the rival coalition’s attempt to spoil the reputation of the institute. The RCC Doctors’ Association and the Employees Association demanded action against Dr. Bhattathiri and Dr. Gangadharan who took the dispute into the public, on the grounds of the violation of service rules.\textsuperscript{97} They also asked \textit{Surya TV} and rival doctors to withdraw from their attempt to tarnish the image of the RCC and frighten patients, thereby creating distrust in the institute among the public.\textsuperscript{98} Both the organisations declared their solidarity with the RCC director.\textsuperscript{99} The Health Minister of Kerala also criticised the attempts to tarnish the institution, and warned against the conspiracy

\textsuperscript{91} “RCCye Nasippikkaruthu: Mukhyamanthri”, \textit{KK}, 03.08.2001, p.3.
\textsuperscript{92} M. N. Vijayan, “RCC”, \textit{Deshabhiman} Weekly Magazine, 33/10, 12.08.2001, p.12. He was the chief editor of the magazine. In the next issue (33/11, 19.08.2001), the magazine published the RCC controversy as its cover story.
\textsuperscript{94} Ibid.
\textsuperscript{95} Ibid.
\textsuperscript{96} “RCC: Mukhyamanthriyude Prashthavana Dourbhagyakaram”, \textit{M}, 04.08.2001, p.7.
\textsuperscript{97} “RCCye Thakarkkan Sramam: Jeevanakkar”, \textit{MM}, 03.08.2001, p.2; “RCCye Thakarkkan Goodalochana”, \textit{D}, 03.08.2001, p.8; “RCC Directorku Pinthunayayi Doctorsum Staffum”, \textit{KK}, 03.08.2001, p.11.
\textsuperscript{98} Ibid.
\textsuperscript{99} Ibid.

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mounted on RCC and its dedicated director. Similar charges of character assassination of the director and the defacement of the institute was raised by many other actors too. Many of them demanded calling off of the dispute till the reports of the enquiry commissions were published or made public.

The involvement of the JHU in the controversy urged the regional press to report the international spill over of the dispute concerning the RCC clinical trials. It was reported in the regional press that the JHU had appointed a three-member commission to investigate the allegations against its involvement in the clinical research. The Madhyamam emphasised that in the preliminary investigation undertaken by the university it was made clear that Dr. Ru Chih C. Huang had not sought permission from the scrutinising body of the university to carry out the research. The regional newspapers took note of a move in the USA to amend the export law of the country to delimit such clinical trials on patients in third world countries. A journalistic report that had been published in the Washington Post titled “The Body Hunters” on clinical trials performed by Western researchers in third world countries stirred up a big debate in the USA. The concerned law was amended in the wake of this uproar, so as to prevent the export of those drugs which were still undergoing clinical trials in Afro-Asian countries. After a few days, the Madhyamam published another report quoting the peer-reviewed journal, Science. According to the newspaper Dr. Manoj Pandey, one of the members of the RCC research team disclosed to Science that the RCC had received $19,400 for the clinical trial. The newspaper presented it as strong evidence against the JHU’s disclaimer

102 See “RCC: Vivadam Venda”, MM, 05.08.2001, p.2.
104 Ibid.
106 Ibid.
107 Ibid.
on its collaboration with the RCC. Quoting the report in *Science*, the *Madhyamam* attempted to expose the controversial tie-up of the university with a drug company to conduct clinical trials in four more Asian countries. The newspaper reported the alleged involvement of a foreign drug company called 'Quintiles' in the RCC clinical trial.

Thus, a controversy originating in the violation of ethical codes in an institution had now snowballed into a larger critique of unethical practices that characterised the world of medical research. Several civil society organisations intervened in the dispute at this juncture demanding a fresh enquiry into the issue and arguing for better regulatory measures in medical research. The IMA-Kerala noted that the allegation against the RCC deserved utmost attention and themselves constituted an independent committee to investigate the case. The Kerala faction of the Indian Pharmaceutical Association as well as the *Prathikarana Vedi* demanded a more democratic, non-partisan and transparent enquiry by a committee consisting of experts from different backgrounds. The KSSP and the Human Rights Protection Council of India demanded strong action against those who conducted unethical and inhuman research at the RCC. The *Prathikarana Vedi* conducted its own investigation into the matter and submitted a study report to the CM, which found the RCC administration guilty of not following the guidelines for clinical trials as stipulated in the Drugs and Cosmetic Rule of 1988. The report noted that the ethical committee in the RCC was not constituted in compliance with the accepted standards.

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110 Ibid.
111 Ibid. The article being quoted here is possibly Bagla and Marshall 2001.
112 "Ibid. *Mathrubhumi* however mentioned it as the 'Quintiles International' and described it as a contract research organisation that operated from the USA. See "Marunnu Pareekshanan: Koodeval Videsa Agencykalkku Panku", *MB*, 12.08.2001, p.5. For similar allegations regarding the involvement of a Singapore based drug company, see "Marunnu Pareekshanan: Koodeval Samsayangal", *MB*, 03.08.2001, p.5.
113 "RCC Vivadam IMA Sanghom Anweshikkum", *MB*, 03.08.2001, p.2; "RCC: IMA Theliveduppu Thudangi", *D*, 05.08.2001, p.4; IMA Commission Theliveduppu Thudangi", *MM*, 05.08.2001, p.9.
114 The Prathikarana Vedi ('Response Forum') was launched at Thiruvananthapuram with an intention to fight corruption. The reputed media analyst Babu Bhaskar was the president of the forum. See "Azhimathikkethire Prathikarana Vedi Roopeekarichu", *KK*, 04.07.2001, p.10.
115 "RCC Vivadam IMA Sanghom Anweshikkum", *MB*, 03.08.2001, p.2; "RCC Vivadam: Sarkar Committee Apanyaphamennu Prathikarana Vedi", *M*, 05.08.2001, p.3.
The forum also alleged that the Helsinki Declaration which safeguarded patients' rights was violated by the RCC.\textsuperscript{118} Seminars were organised on the controversy by several organisations, discussing the pros and cons of the issue.\textsuperscript{119} Most of them discussed the controversy in the light of the corrupt practices that afflicted medical research.\textsuperscript{120}

The internal dynamics of medical research in the globalised world thus became an open subject of public debate in the context of the clinical trial controversy. The endeavour to use people of the developing countries as guinea pigs and the operations of multinational drug companies were emphasised as grave concerns in the scientific public sphere at this juncture, thanks to the persistent effort of the Malayalam press to report the debates taking place in the Western media to its readers. This linking of regional concerns with the debate in the West facilitated the expansion of the scope of the regional deliberations and the wider involvement of civil society organisations.

4.2. Voices of the Patients

The patients who had been subjected to the drug trial appeared as actors in the scientific public sphere at this juncture, as a result of the organised effort of the rival coalition. Dr. Gangadharan, Advocate Vincent Panikkulangara and the Madhyamam were the key players who attempted to bring in the voices of the patients. The Madhyamam published an exclusive report on the victimisation of the patients, presenting the case of a patient named Gopal, who was suffering from cancer on the tongue.\textsuperscript{121} The report was based on an interview with the patient who was from Tamil Nadu. Gopal was quoted to be suggesting that he was unaware of the clinical trial. He alleged that when the drug was injected on his tongue he had been told that it was a local anaesthetic administered to remove the malignant tissue.\textsuperscript{122} The report pointed out that the document which explained the nature of the experiment that Gopal was to

\textsuperscript{118} Ibid.

\textsuperscript{119} Seminars organised by the Mukthi, the IPA-Kerala, the KSSP and the Kerala M. Pham Students' Forum had widely been reported in the regional press. See news reports on 04.08.2001 and 08.08.2001.

\textsuperscript{120} KSSP was the most vocal speaker in this regard. It also strongly demanded that the ICMR guidelines should be made applicable for all medical science research institutes in the country. See RCC Pareekshanam: Nadapadi Venamennu Parishad", \textit{MM}, 08.08.2001, p.9; "Uttharavadikale Matti Nirthi Anwesikkanam: Parishad", \textit{D}, 08.08.2001, p.6; "RCC: Vazhivitta Pareekshanaththinethire Nadapadi Venam: Sastra Parishad", \textit{KK}, 08.08.2001, p.2.

\textsuperscript{121} "'Guneappanni' Ayathu Aarkku Vendiyennariyathe Gopal", \textit{M}, 03.08.2001, p.5.

\textsuperscript{122} Ibid.
undergo was in English and Malayalam, and therefore he could not follow its contents, as he knew only Tamil.\textsuperscript{123} The drug did not produce any positive change in him and that he had to come back again with throat cancer, according to the news report. The newspaper hinted that this could have been caused by the drug being administered on him.\textsuperscript{124} Gopal filed a complaint against those involved in the clinical trial with the Human Rights Commission (HRC) of Kerala with the aid of his advocate Vincent Panikkulangara.\textsuperscript{125} Dr. Gangadharan also appeared before the Commission and alleged that the drug had been administered to his patient without his consent.\textsuperscript{126}

Later, Advocate Panikkulangara appeared before the Parikh Commission and stated that two of the patients who had been administered the drug died within fifty days, and submitted the case documents from the RCC as evidence.\textsuperscript{127} The son of Lalithamma, one of the patients who allegedly died after undergoing the clinical trial, approached the enquiry commission appointed by the Central Government and complained that his mother passed away after being subjected to the clinical trial.\textsuperscript{128} The RCC director denied such charges pointing out that Lalithamma was a chronic cancer patient in the last phase of her sickness and therefore her death was not caused by the drug administered to her.\textsuperscript{129} On the very day when Gopal’s story appeared in the \textit{Madhyamam}, a joint meeting of the staff associations of the RCC alleged that the rival scientists were trying to provoke people by propagating the idea that the clinical trial was carried out on dalit patients.\textsuperscript{130} They also criticised the media for selectively presenting the case of terminal patients before the public.\textsuperscript{131}

The strong opposition to the discourse on patients’ rights eventually lost ground, apparently because of the lack of convincing medical evidence to substantiate the claim that the patients developed secondary tumours due to the drugs under trial. Although the attempt to raise the question of patients’ rights failed to be properly

\textsuperscript{123} Ibid.
\textsuperscript{124} Ibid.
\textsuperscript{125} "Gopal Manushyavakasa Commissionu Parathi Nalki", \textit{M}, 03.08.2001, p.2.
\textsuperscript{126} "Gopalil Pareekshanam Nadathiayathu Chattangal Lankhicchu", \textit{M}, 18.08.2001, p.2.
\textsuperscript{130} "RCCye Thakarkkan Sramam: Jeevanakkar", \textit{MM}, 03.08.2001, p.2.
\textsuperscript{131} Ibid.
articulated, the image of the patient’s body as subjected to the unethical and harmful drug trials by the medical research establishment had been actively maintained in the deliberations.

5. ‘Safeguard the RCC!’ The Consensus

However, a general consensus about safeguarding the status of the RCC as a reputed medical research institution began to emerge in the scientific public sphere. At the same time, it is evident that the crystallisation of this consensus did not close the controversy; the deliberations continued, but most of the actors agreed on defending the institution while continuing to debate the issues involved. This consensus was accomplished through the concerted campaigning of a wide range of pro-RCC actors. The campaign was conducted by those who supported the RCC administration and the director had an important role to play in achieving this consensus. Although the need to safeguard the institution began surfacing since the CM’s plea to the public, it was the literati of Kerala who forced it as a central concern for all Keralites. They signed an open joint letter that requested the public to desist from tarnishing the institution while criticising the clinical trials.132 Many of the intellectuals used the ‘Letters to the Editor’ columns as well to express their concerns.133 The ‘RCC Protection Forum’ was a general platform created exclusively for the purpose of the campaign by the pro-RCC actors, mainly the staff of the institute. They had rigorously campaigned against any attack on the RCC through demonstrations, public meetings and press conferences.134

The Kerala Kaumudi was a major actor who supported the campaigners by relentlessly voicing their concern and reporting their campaigns. The newspaper strongly defended the RCC and its director in its editorial on 18 August.135 The editorial argued that Dr. Krishnan Nair must not be criticised, as he was the sole

132 See “RCCyude Visvasyatha Nashtappedutharuthu”, MB, 19.08.2001, p.3; See also the personal requests made by some of the signatories; Vishnu Narayanan Nampoothiri, “RCC Erinjudaykkaruthu”, MB, 15.08.2001, p.4, editorial page article; “RCC Vivadam Sthapanathinte Nadathippinu Bheeshaniyakanthu: ONV”, MM, 17.08.2001, p.17.
134 See “RCCkkethire Pracharanam Nadathiyavare Pirichu Vidanam”, D, 20.08.2001, p.8. It is also interesting to note that while the entire RCC staff and their organisations defended the institution, most of the youth wings of political parties (especially the AIYF, the DYFI and the Youth Congress) came out against the RCC and demanded strong action against the culprits.
person who created the institution from almost ‘nothing’. The ‘Letters to the Editor’ column was meticulously utilised by the Kerala Kaumudi to articulate the campaigners’ concerns. The newspaper skilfully selected and published letters to the editor as a powerful tool while voicing its own concerns as readers’ opinion. This was accomplished mainly by organising the column in such a way that the majority of letters appear to be expressing the views and interests of the newspaper, while publishing a few letters presenting counter-arguments. Most of the letters that appeared in the newspaper expressed the readers’ reservations concerning the orchestrated attempt at character assassination of the RCC director, which was seen as a serious threat to the reputation of and public trust in the institute. Some of the letters supported the statement of the CM and in so doing defended the institute and the director. Many readers attacked the rival group of scientists for their ulterior motives. As mentioned earlier, some of the letters attempted to link the controversy to the wider debate on ethics in medical science research. One reader, for example, invited public attention to the fact that several of the drugs banned in the West were still in use in India. This unethical evasion of all regulatory measures was indicative of the larger malaise exemplified by the RCC clinical trials, the letter argued. Another reader, a doctor by training, expressed the same concern by pointing to the unholy alliance between doctors and multi-national drug companies. As a solution, he suggested that medical research be restricted to universities and demanded the

136 Ibid.
137 Mathrubhumi also used its letter to the editor column in a similar fashion, but more benignly. See for example, Sugathakumari, Thiruvananthapuram, “RCCyude Agnipareeksha”, MB, 09.08.2001, p.4, letter to the editor; ONV Kurup, “RCCye Nasippikkaruthu!”, MB, 17.08.2001, p.4, letter to the editor. The construction of the ‘Letters to the Editor’ columns by the press to further its interests is a well-noticed fact. See Richardson and Franklin 2003. For a detailed discussion on the letters to the editor as a genre, see the next chapter.
138 Adv. V. Sadasivan, “Cancer Centre Vivadam”, KK, 05.08.2001, p.4, letter to the editor; Dr. K. Balaraman (Former director, Dept. of Health), Thiruvananthapuram, “RCC: Kolahalam Apalapaneeyam”, KK, 07.08.2001, p.4, letter to the editor.
139 See for example, Umayannur E. Asseem Kunju, Perayam, “RCCye Nasippikkaruthu”, KK, 06.08.2001, p.4, letter to the editor.
141 Priyanjana Prabhakar, Thiruvananthapuram, “Athu Mathramo Nirodhikkappetta Oushadham?”, KK, 05.08.2001, p.4, letter to the editor.
142 Ibid.
proscription of all research projects being carried out for foreign agencies.\textsuperscript{144} He also suggested the formulation of a new drug policy that curtails unethical and inhuman practices in the medical science by stricter regulatory measures.\textsuperscript{145} The genre of letters to the editor was not widely used in this manner by other newspapers in the clinical trial controversy.

Such an organised campaign had a deep impact on the course of the dispute. The consensus shared by the actors irrespective of their affiliations was that the prestige and reputation of RCC as a medical institution had to be safeguarded by delimiting the public criticism to the issue of malpractices in medical research. Even the opponents of the clinical trials softened their attack against the RCC as an institution. This is quite evident from a later statement of Dr. C.R. Soman; it was stated that he did not have any intention to malign the institution, but his criticism was directed against the unethical clinical trials.\textsuperscript{146} The letter to the editor from a reader who identified himself as a medical doctor was highly suggestive of the mood that prevailed in the scientific public sphere. The reader defended the RCC, while strongly recommending an immediate moratorium on the controversy pointing out that an enquiry into the matter was already on.\textsuperscript{147} In the same vein, he acknowledged the prevalence of unethical practices in the medical sciences and demanded punitive action against those who prove to be guilty.\textsuperscript{148} Thus, the RCC as a medical institution of high repute was strongly defended while the criticism was successfully being relocated to the unethical medical research practices and those who were responsible for such acts that had jeopardised the name of the institution.\textsuperscript{149} The consensus thus achieved at this stage indicates how the ideology of neutrality functioned in science:

\textsuperscript{144} Ibid.
\textsuperscript{145} Ibid.
\textsuperscript{146} Dr. C.R. Soman, “Cancer Centreine Apakeerthippeduthukayalla Lakshyam”, KK, 12.09.2001, p.4, letter to the editor.
\textsuperscript{147} Dr. P.A. Kurup, Thiruvananthapuram, “Marunu Pareekshanam: Reportinu Kakkuka”, MB, 23.08.2001, p.4, letter to the editor.
\textsuperscript{148} Ibid.
\textsuperscript{149} Similar letters employing the same argumentative technique appeared in later numbers. See for example, Dr. K. Balaraman, “RCC: Kolahalam Apalapaneyam”, KK, 07.08.2001, p.4, letter to the editor; Dr. N.M. Muhammad Ali, “Verittoru Sabdam”, KK, 19.08.2001, p.4, letter to the editor; Dr. T.P. Gopalakrishnan, Kawadiyar, Thiruvananthapuram, “Doctormar Porvili Nirthanam”, MB, 23.08.2001, p.4, letter to the editor; Ramesh G., Kozhikode, “RCCyude Salpperu Nilanirthan”, MB, 14.09.2001, p.4, letter to the editor. Note that several of the readers who defended the RCC were physicians by profession. Many of them found the allegations against the RCC clinical trial as a threat to the autonomy of the medical establishment itself, and thereby to their own professional authority. It clearly indicates how the professional interests motivate speakers to participate in a controversy. For a detailed discussion, see Martin 1988.
the RCC as an institution was seen as essentially good, and it was some ‘bad scientists’ to be blamed for anti-human practices in modern science.

6. From Consensus to Closure

The closure of the controversy was attained in the following months as a result of fresh developments followed by the appointment of the enquiry commissions. It can be seen that four such investigations were on during this phase; the Parikh Commission constituted by the state government, the commission sent by the central government, the Human Rights Commission, and the enquiry instituted by the IMA-Kerala. The investigations of these bodies became the focal point of attention in the regional press in the last phase of the dispute. It is noticeable that these enquiries also bore the brunt of public criticism.

The rival coalition attempted to question the credibility of the commissions instituted by the state and central governments on different grounds. The Health Ministry Commission that arrived in the state capital on 8 August for carrying out the investigation was critiqued by the Madhyamam. In its very first report on the commission, the newspaper indicted that the commission had not had a proper orientation regarding the mode of enquiry. The newspaper also reported the dubious presence of two vehicles from the RCC at the airport when the commission members arrived. The news report hinted that these vehicles seemed to arrive at the airport to receive the commission, and thus indicative of the hidden nexus between the government and the RCC administration.

The Parikh Commission commenced its hearing on 9th August. The same newspaper reported that Dr. Parikh arrived for the hearing in a vehicle provided by the RCC. The news report alleged that the assistant of the commission belonged to the RCC staff. In another news report, the Madhyamam argued that it was a

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150 The commission was constituted by the Union Ministry of Health and Family Welfare. The commission consisted of Dr. A.R. Singh (representative of the DCGI), Dr. Vasantha Muthu Swami (ICMR) and Dr. A. N. Serin (consultant, Dept. of Paediatrics, Nirman Bhavan). See “Cancer Centre Vivadam: Kendra Sanghom Ethi”, M, 09.08.2001, p.5.
151 “Cancer Centre Vivadam: Kendra Sanghom Ethi”, M, 09.08.2001, p.5. The Mathrubhumi also reported the ambiguity regarding the aims and objectives of the enquiry. See “RCC Anweshana Sanghom Ethi”, MB, 09.08.2001, p.5.
152 Ibid.
153 Ibid. However, the same news report agreed that they travelled in the vehicles provided by the Department of Health.
155 Ibid.
member from the personal staff of the RCC director who accompanied Dr. Parikh.¹⁵⁶ It was alleged that the Parikh Commission was a charade staged by the state government hand-in-glove with the RCC administration to salvage the culprits.¹⁵⁷ Dr. Bhattathiri declared that he would not cooperate with the Parikh Commission and demanded the constitution of an expert commission comprising of experts from different fields by replacing the single-member commission.¹⁵⁸ This argument gained wide currency as organisations like the KSSP and the All India Youth Federation (AIYF) supported the demand.¹⁵⁹ Dr. Parikh denied all charges against the credibility of the commission and assured a just and transparent investigation on the controversial clinical trials.¹⁶⁰ The Human Rights Commission was not criticised by the anti-RCC group of actors, because its functioning was indirectly supportive of their cause since the beginning.

6.1. The Coup

In the days that followed, the regional press began reporting the functioning of the Parikh Commission, the Health Ministry Commission and the Human Rights Commission on a regular basis. The newspapers reported the statements made before the commissions by a wide range of people who were involved in the controversy. It was at this point that the Kerala Kaumudi attempted to steer away the whole controversy in another direction in favour of the RCC. The investigative news report by P.V. Murukan was influential and it presented certain ‘evidence’ for the hidden agendas of the rival group of scientists.¹⁶¹ According to the report, Dr. Bhattathiri and Dr. Gangadharan, two scientists who sparked off the controversy had registered a cooperative society with the intention to start a cancer treatment and research institute at Kollam.¹⁶² The report alleged that the controversy was a vicious and concerted endeavour to create public distrust in the RCC in order to promote the new hospital

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¹⁵⁶ Ibid. See also “RCCyude Vahanam Sarkar Nalkiyathennu Thettidharichu”, M, 11.08.2001, p.7.
¹⁵⁸ “RCC Anweshanam Nale Thudangum”, D, 08.08.2001, p.6.
¹⁶¹ “Vivada Marunnu Pareekshikkappetta Rogikali Ninnu Thelivedukkum”, KK, 11.08.2001, p.3.
¹⁶³ Ibid. The news report also mentioned that some more persons from the RCC were involved in the venture.
and research institute the rival scientists were planning to establish. The report appeared as a piece of investigative journalism; however it was not an exclusive one. The Malayala Manorama, another strong defender of the RCC, on the same day reported the sealing of the documents of registration of the ‘Janatha Health and Radiation Research Society’ by police on a request from Dr. Krishnan Nair. The appearance of the news on the same day in the Malayala Manorama suggests that seemingly it was Dr. Krishnan Nair who was behind the expose with the help of the newspapers which were his close allies in the dispute. The registration of the Society was apparently an already known fact among the scientists and staff of the RCC, but revealed by the RCC director at this decisive moment to win over the rival scientists.

The report of Kerala Kaumudi had a big impact on the controversy, as the legitimacy of the rival scientists was challenged by the published allegation. Most of the newspapers reported the matter in the days that followed. The pro-RCC speakers effectively manoeuvred the situation to their advantage: the RCC Protection Forum attacked their opponents virulently and demanded immediate dismissal of those who were involved in the venture. The Madhyamam endeavoured without much success to arrest the set back by publishing an exclusive report on the financial side of the clinical trial. According to the report, the RCC had received Rs. 40 lakhs from the JHU as remuneration, and the money was kept in a special bank account directly controlled by the RCC director. The news report alleged that this was indicative of the financial corruption involved in carrying out research. The newspaper revealed that foreign funds received by the institute for the purpose of research were not audited for several years, further reinforcing charges of financial corruption in the institute.

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163 Ibid.
164 "RCC-Paraathiyil Puthiya Society Rekhakal Mudra Vechu", MM, 22.08.2001, p.13. The report explained that seven doctors from the RCC were involved in the registration of the Society.
166 "RCCkkethire Pracharanam Nadathiavare Pirichu Vidanam", D, 29.08.2001, p.8; "RCC: Nalu Perkkethire Parathi", D, 24.08.2001 p.3; "RCC Protection Forum Prakshobhatilekku", KK, 28.08.2001, p.3; The forum went a step further when it filed a petition against Dr. C.R. Soman who spoke against the clinical trial, alleging that he indulged in a slander campaign against the RCC. See “RCC Vivadam: Dr. C.R. Somanethe Protection Forum Paraathi Nalki”, D, 09.09.2001, p.3.
167 "Cancer Centreinu Hopkins Nalkiyathu Naalpathu Lakhsham: Thuka Prathycka Accountii", M, 28.08.2001, p.1. The news report published a photograph of the receipt of the money sent by the manager of the bank to the RCC director as evidence for the same.
168 Ibid.
6.2. The Enquiry Reports

The endeavours of the rival scientists and their allies to fight back further proved unsuccessful when the investigative reports of the enquiry commissions were released. All the reports shared the consensus that had already been attained in the scientific public sphere; that the credence of the RCC as a medical research institution must not be tampered with. Therefore all the commissions who published their reports mostly recommended revision of the medical research guidelines to avoid violation of research protocols.

The Commission of the Health Ministry submitted its enquiry report and the Ministry promptly suspended all the ongoing human drug trials at the RCC for six months. The enquiry report revealed that the Indian Council of Medical Research (ICMR)'s guidelines for research were not followed by the RCC in setting out the clinical trials. According to the enquiry report, the research had been carried out in collaboration with the JHU and the drug involved was a derivative of M4N. The enquiry commission also said that research had commenced well before permission was granted by the DCGI. However, the report emphasised that there were no human rights violations involved in the clinical trial and instead highlighted the violation of research protocols. The report also pointed out that the specimen collected from the patients had been sent to the JHU without permission from the concerned regulatory bodies. On the basis of the report, the Health Ministry sent a show-cause notice to the RCC and directed the institute to reconstitute its ethics committee. The government decided to make the ICMR guidelines for medical

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It was reported that punitive action against the accused would be sought by the government. However, this was later rejected by the Health Ministry of India on the ground that the drug used for the clinical trial was not banned, thereby avoiding any severe action against the institution.

The IMA-Kerala published also its report around this time. This report maintained an analogous position on the dispute. The enquiry committee strongly recommended that no punitive action be taken against the scientists, as it would affect the reputation of the institute. Nevertheless, their report pointed out that the research guidelines had been violated as the RCC imported the drug before permission was granted by the DCGI. The report absolved the RCC scientists of all charges of human rights violations and asserted that the clinical trial was transparent and devoid of any vested interest. It was also pointed out that M4N was not a banned drug. The action of scientists for raising the matter in the media rather than ‘handling it officially’ was staunchly criticised in the report.

Both the reports invited public criticism. The Deshabhimani saw the report of the Commission of the Health Ministry as an attempt to hush up the controversy. The newspaper opined that by rejecting the charge of human rights violations in the clinical trial, the report of the commission successfully safeguarded the scientists and the RCC administration from any strong punitive action. The Madhyamam alleged that by publishing its report, the IMA was attempting to rescue the RCC. It was also noted that the original report of the IMA had been redrafted for the same

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176 Ibid. Earlier the twelve guidelines of the ICMR were applicable only to the research institutions under the ICMR.
182 Ibid.
purpose.\textsuperscript{186} Dr. V.N. Bhattathiri opposed the finding of these reports that there was no violation of human rights involved.\textsuperscript{187}

The Human Rights Commission took cognisance of the conclusion of these reports that there were no human right violations involved in the clinical trial. The chairperson of the HRC, Dr. S. Balaraman pointed out that it was the HRC’s responsibility to investigate whether human rights violation was involved in the clinical trial, and observed the action of these commissions as infringing on the powers vested in the HRC.\textsuperscript{188} On the basis of the media reports as well as a complaint filed by an individual, Dr. Balaraman sent a notice to the Health Ministry Commission asking it to submit its enquiry report before the HRC.\textsuperscript{189} He asserted that human rights violations had prima facie taken place in the RCC clinical trial.\textsuperscript{190}

The Parikh Commission’s preliminary report was made public on 4 October and it was more sympathetic to the RCC.\textsuperscript{191} The report observed that other than ‘minor procedural errors’, the clinical trial was not erroneous.\textsuperscript{192} According to the report the research agreement between the RCC and the JHU was transparent.\textsuperscript{193} The commission pointed out that the drug used was not banned and it was effective when administered to patients and no side effects were reported.\textsuperscript{194} It was asserted in the report that prior consent had been given by the patients.\textsuperscript{195} Similar to the IMA report, the Parikh Commission report also criticised the rival scientists for creating a public

\textsuperscript{186} Ibid.
\textsuperscript{188} RCC Vivadam: Anweshana Report Haajarakkanam”, \textit{MM}, 20.09.2001, p.7; “Kendra Anweshana Sanghatinu Manushyavakasa Commissione Notice Ayachu”, \textit{D}, 20.09.2001, p.6; “Marunnu Pareekshhanam: Kendra Anweshana Sanghatinu Manushyavakasa Commissione Notice”, \textit{M}, 20.09.2001, p.10.\textsuperscript{189} Ibid. It was also stated by the chairperson of the HRC that notice would be sent to the IMA-Kerala as well.
\textsuperscript{190} “Marunnu Pareekshhanam: Kendra Anweshana Sanghatinu Manushyavakasa Commissione Notice”, \textit{M}, 20.09.2001, p.10. The progress of the investigation being carried out by the HRC remained under-reported in the regional press thereafter. An actor who was very involved in opposing the clinical trial told me that Dr. Krishnan Nair silenced the HRC through skilful backstage operations.\textsuperscript{191} \textit{Malayala Monorama} was the only newspaper which reported the content of the preliminary report. Others published the news when the final report was submitted to the government one month later.
controversy over the issue by misleading the media. The report also demanded fresh investigations into the dubious role of Dr. Bhattathiri in creating public controversy. The commission, however, suggested reconstitution of the ethical committee of the RCC.

The Parikh Commission report invited much criticism from the allies of the rival scientists. The Madhyamam staunchly opposed the findings of the commission, arguing that the commission’s findings relied exclusively upon the narrative of the RCC administration. The commission failed to answer whether NDGA, the banned drug, had been administered in the clinical trial, because the report did not make it clear whether M4N was a derivative of NDGA, the news report contended. The newspaper challenged the claim of the commission that clinical trials had been ‘scientifically administered’, pointing out that the premise of the statement was not clear. The Madhyamam alleged that the Parikh Commission had been taking a pro-RCC stance since its inception and criticised its attempt to ‘frame’ Dr. Bhattathiri. In another report, the newspaper asserted that the reports of the Parikh Commission as well as the commission appointed by the Health Ministry were orchestrated attempts to absolve the RCC scientists.

Quite contrary to the above mentioned enquiry reports, the conclusions of the JHU Enquiry Committee were against the principal researcher, Dr. Ru Chih C. Huang. The enquiry report published by the JHU revealed that she did not follow the guidelines of the university as well as the scientific protocols for clinical trials. The JHU enquiry committee also assessed that the clinical trials undertaken at the RCC had several shortcomings. Based on the enquiry report, the university prohibited Dr. Huang from being the principal investigator in human drug trials.

197 Ibid.
198 Ibid.
199 Ibid.
200 Ibid.
201 Ibid.
202 Ibid.
203 Ibid.
205 Ibid.
206 Ibid.
207 Ibid.
208 Ibid.
209 Ibid.
210 Ibid.
211 Ibid.
212 Ibid.
The reports of different enquiry commissions invited a range of responses. The *Prathikarana Vedi* criticised the Parikh Commission report for its lack of transparency and urged the chief minister not to be part of the governing bodies of institutions like the RCC. The EMS Cultural Forum organised an open debate in which Dr. C.R. Soman maintained that the clinical trial was illegal and unethical. He reiterated the point that human rights of the patients had been violated. Many of the speakers in the debate demanded punitive action against the RCC director. The Democratic Youth Federation of India (DYFI) strongly criticised the Parikh Commission for showing clear partiality toward Dr. Krishnan Nair. The DYFI state secretary T. Sasidharan pointed out that the JHU enquiry report made it clear that the clinical trial was unethical and he impugned the lack of will power on the part of the state government to take action against the harmful rackets witnessed at the RCC. On the contrary, the *Kerala Kaumudi* published an editorial page article and a news report strongly supporting the findings of the commissions and criticising the tendency to pursue the controversy even after the enquiry reports had been published.

Since the reports had been published, the state and central governments began explicitly defending the RCC and the clinical trial. The union health minister Dr. C.P. Thakur told the Parliament that the banned drug had not been experimented in the RCC and therefore human rights were not violated. The state minister of health P. Sankaran also declared the same in the state legislative assembly, though the opposition staunchly criticised the government and the Parikh Commission. The

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209 Ibid.  
210 Ibid.  
212 Ibid.  
213 See, Dr. Raveendran Kummil, “RCC Vivadavum Vasthuthakalum”, *KK*, 30.11.2001, p.4, editorial page article; “RCC Vivadam Arthasoonyam: Dr. Padmanabhan Nair”, *KK*, 11.02.2002, p.2. The latter news report was based on an interview with Dr. Padmanabhan Nair, who was the former director of the Department of Biomedical Research at JHU. He claimed that it was he who introduced Dr. Ru Chih Huang to Dr. Krishnan Nair.  
opposition alleged that the United Democratic Front (UDF) government was safeguarding the RCC director and the scientists, instead of taking action against their unethical research practices and human rights violations. The opposition demanded the immediate scrapping of the Parikh Commission report for its contradictory and counterfactual findings and urged the government to order a fresh enquiry by a panel of experts. However, the health minister of Kerala reiterated that any false propaganda against the RCC would affect its reputation, although the government was willing to enquire into any complaint against the institution. Based on the assessment of a cabinet sub-committee, the report of the Parikh Commission was accepted by the government on February 2002. It can be seen that even before the acceptance of the report by the state government, the controversy had actually died out. The scientific public sphere which was constituted around the dispute had started dispersing some time ago, since the moral agency of the rival scientists who opened the controversy was constantly challenged and finally denied in the scientific public sphere.

7. Conclusion

A study of the RCC clinical trial controversy clearly indicates that the dispute exhibited a totally different dynamics, contra to the controversies we have examined in the previous chapters. The most crucial difference is that the regional press functioned in this case not as the prime site where the dispute first surfaced. As we have seen, the issue was taken up by a news channel and some civil society organisations, and then gradually the regional press turned to be the major site of deliberations. Further, there existed parallel sites of negotiations throughout the controversy. Even though the regional press functioned as the major scientific public sphere, several platforms were constituted as ‘parallel scientific public spheres’ or as ‘counter scientific public spheres,’ which had a deep impact on the deliberations in

the main scientific public sphere, constituted through the regional press.\textsuperscript{220} The debates in these counter/parallel scientific public spheres had been registered in the regional press, and these debates were frequently pursued by the latter.

Another aspect of the RCC clinical trial controversy was the perceptible existence of a strong filtering mechanism that largely determined the course of the deliberations on the front stage. The regional press in the beginning of the controversy attempted to regulate the dispute in an explicit manner and many of the newspapers were strong allies in the mutually contending coalitions. The dynamics of the journalistic production of news—the backstage activities—which shaped the front stage became more explicit in the RCC clinical trial controversy than in the other two cases. However, this does not imply that the deliberations in the scientific public sphere were completely engineered by a hidden network functioning behind the scene. On the contrary, the course of the deliberations was determined by a complex process of dialectical engagement between the back and front stages, wherein the regional press functioned as the mouthpiece for many of the actors and their coalitions. At the same time, the newspapers were pushing their own agendas and interests, shaping the controversies. It shows that the newspapers were functioning simultaneously as agenda brokers and controversy makers by playing their role as managers of the backstage as well as actors on the front stage. This double role of the newspapers that determines the structure and function of the scientific public sphere will be the focus of the next chapter.

\textsuperscript{220} Nancy Fraser argues that the main public sphere always exists in constant engagement with parallel sites of negotiations, which she calls 'counter public spheres'. She points out the existence of women’s movements as an example for counter public spheres which push the feminist agendas into the masculine, mainstream public sphere. See Fraser 1995.