Materials
And
Methods
Hyperlipidemia:

Subject Selection:
The study population includes subjects/patients from Ahmedabad city and rural areas around Ahmedabad, Gujarat, India with varied life style based on their occupation who presented to outdoor patient department (OPD) of department of medicine were screened and selected for the study. Both men and women, age ranging between 18 to 60 years, were screened and those who were diagnosed as hyperlipidemic on the basis of their abnormal serum lipid profile towards higher side compared to the mentioned recommended lipid and lipoprotein nomograms in Indian populations and recommended levels (mean value in mg/dl) [API text book of Medicine; 6th edition] and who fulfilled the inclusion and exclusion criteria were selected for the study.

After one-week interval, estimation of serum lipid profile was repeated again (that value will be considered as base line value) and thereafter those subjects who had particularly abnormal (higher) triglyceride level were again examined by screening physician for clinical history and presence of any other disease.

Inclusion criteria:

1. Males and females within age group of 18-60 years.
2. Abnormal lipid profile towards higher side compared to the mentioned recommended lipid and lipoprotein nomograms in Indian populations and recommended levels.
3. Subjects who were willing to get enrolled in the study and gave written informed consent.

Exclusion criteria:

1. Subjects / patients with any known food allergies.
2. Subjects / patients with history of present or past smoking.
3. Subjects / patients with history of hypertension or any other cardiovascular disease.
4. Subjects / patients with history diabetes mellitus.
5. Subjects/patients with any other abnormal laboratory parameters.
6. Subjects/patients who were taking any medication for their hyperlipidemia on regular basis.

7. Subjects/patients who were taking any other nutraceutical medication/supplements on regular basis.

8. Any subject/patient who according to screening doctor was considered unable to comply with the study protocol.

9. Pregnant and lactating females.

10. Subjects/patients who was suffering from any other concomitant chronic condition, which could worsen during the study period necessitating removal of patient/subject from the study.

11. Any subject/patient who was unwilling to give written informed consent.

Study Design:

- The purpose/nature of study, study protocol and nature of test drug was explained to the subjects in their local language. After understanding that, out of 148 subjects, 120 subjects willingly gave written consent to participate in the drug trial.

- A randomized placebo controlled, single blinded study designed was used to compare the hypolipidemic effects in placebo and test-drug treated subjects. All 120 subjects were randomly divided into two groups, group-A and group-B. Each group consist 60 subjects respectively. Group-A served as placebo controlled and group-B served as test group.

- Laboratory estimation for serum lipid profile values, BT, CT, PT, RFT, LFT, FBS as well as BP (blood-pressure) measurement was carried out in subjects of both groups and the obtained values were labeled as base line values (0-day values).

- Then both group subjects were instructed to reduce in dietary fat consumption by ≈30% to their previous daily regular diets for one month (30 days) labeled as restricted diet or phase-1 for both group respectively.
• After 30 days i.e. on 31\textsuperscript{st} day (end of restricted diet or phase-1), serum lipid profile estimation was carried out again and was labeled as end of restricted diet values or phase-1 values.

• The phase-1 was followed by placebo treatment in placebo group and test drug (essential fatty acid [EFA]) with restriction in diet as above for 6 weeks i.e from 31\textsuperscript{st} day to 72\textsuperscript{nd} day of study period and labeled as placebo treated with restricted diet or phase-2 and test drug treated with restricted diet or phase 2 respectively.

• At the end of phase-2, estimation of laboratory parameters, serum lipid profile, BT, CT, PT, RFT, LFT, FBS, as well as blood pressure measurement was repeated. The observed values at the end of phase-2 were labeled as end of placebo treated or phase-2 values and end of test drug treated or phase-2 values respectively. In phase-2 the treatment schedule to group-A and group-B is shown in the table.
### Study plan for hyperlipidemia

<table>
<thead>
<tr>
<th>Work up done</th>
<th>Visit 1 (7 days after visit 1)</th>
<th>Visit 2 (one month after visit 2)</th>
<th>Visit 3 (6 weeks after visit 3)</th>
<th>Visit 4 (6 weeks after visit 3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening including complete physical checkup</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Serum lipid profile</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Laboratory estimation for serum lipid profile values, BT, CT, PT, RFT, LFT &amp; FBS</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Explaining of study design</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Explanation about dietary restrictions</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Informed written consent</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Dispensing of study drug</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Safety assessment/ adverse reaction monitoring</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### Treatment groups:

<table>
<thead>
<tr>
<th>Group</th>
<th>Drug</th>
<th>Strength of drug</th>
<th>Dose</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo- Controlled</td>
<td>Liquid paraffin (Placebo)</td>
<td>1 ml/capsule</td>
<td>2 Cap. – t.i.d. (2 ml – t.i.d.)</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Test-group</td>
<td>LA + ALA (Test-drug)</td>
<td>150mg/Capsule</td>
<td>2 Cap. – t.i.d. (300mg – t.i.d.)</td>
<td>6 weeks</td>
</tr>
</tbody>
</table>

Abbreviation: Cap: Capsule (Soft gelatin capsule); tid.: Three times a day; LA: Linoleic acid; ALA: α-linolenic acid.
Blood samples and laboratory tests:
12 hours fasting morning blood samples were collected for biochemical estimation, initially at the commencement of the study (base line values) and at the end of 6 weeks of placebo and EFAs treatment in both placebo and test groups. Following estimations were done using slandered laboratory methods.

Laboratory tests

Serum lipid profile:

- Serum total cholesterol was determined according to enzymatic method described by Allen et. al., Clin. Chem., 20:470-475 (1974).
- VLDL was determined by a simple mathematical calculation, where VLDL was equal to estimated serum triglyceride value divided by 5, ( VLDL = Tg/5).
- LDL-cholesterol was determined and calculated by using fridwald and fredricksnon’s formula: LDL-cholesterol = Total Cholesterol − ( Tg/5 + HDL-cholesterol).
- In addition to these other routine laboratory investigations such as: Hemoglobin, Total counts, Bleeding time, Clotting time, Prothrombin time, Fasting blood sugar, Liver function test, Renal function test were carried in college pathology and biochemistry laboratory as a routine course.
• Together with these, subjects were instructed to note down or to report to observer for the occurrence of any adverse events or untoward effects with placebo or test drug and if occurs he or she must immediately stop taking given treatment to report immediately to observer.

• Moreover if patients comply the study protocol satisfactorily, at the end of study period their opinion for the tolerability of treatment was ask by verbal communication with the number of subjects completed the study satisfactorily as good or not-good.

Statistical Analysis:
For individual group paired ‘t’ test was performed to find out the significance or non-significance for treatment efficacy in respective group. Whereas, un-paired student ‘t’ test was performed to find out the significance or non-significance for treatment efficacy comparison between two group treatment (placebo & test-drug treatment).

This study was carried out in accordance with declaration of Helsinki and principles of good clinical practice.

ARTHITIS:
Osteoarthritis:
Selection of Patients:

• The study population includes patients from Ahmedabad city and rural areas around Ahmedabad, Gujarat, India with varied life style based on their occupation who presented to outdoor patient department (OPD) of department of medicine / orthopaedics were screened and selected for the study.

• Ambulatory adults of either sex, in a age group of 18 to 70 years with a diagnosis of primary osteoarthritis (OA) of knee according to the clinical /radiological criteria’s of American College of Rheumatology were considered eligible to participate in the drug trial.
Inclusion criteria:
1. Males and females within age group of 18-60 years.
2. Diagnosis of primary osteoarthritis (OA) of knee according to the clinical/radiological criteria’s of American College of Rheumatology.
3. Patients who were willing to get enrolled in the study and gave written informed consent.

Exclusion criteria:
1. Patients were excluded if they had any other musculo-skeletal joint disease.
2. Patients with any known food allergies.
3. Patients with history of hypertension or any other cardiovascular disease.
4. Patients with history diabetes mellitus.
5. Patients with any other abnormal laboratory parameters.
6. Patients who were taking any other nutraceutical medication/ supplements on regular basis.
7. Patient who according to screening doctor was considered unable to comply with the study protocol.
8. Pregnant and lactating females.
9. Patients who was suffering from any other concomitant chronic condition, which could worsen during the study period necessitating removal of patient/subject from the study.
10. Any patient who was unwilling to give written informed consent.
11. Patients with prior replacement surgery or eligible for surgical intervention were not considered for inclusion in the trial.

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Rheumatoid arthritis:
Selection of study patients:
The study population includes patients from Ahmedabad city and rural areas around Ahmedabad, Gujarat, India with varied life style based on their occupation who presented
to outdoor patient department (OPD) of department of medicine/orthopaedics were screened and selected for the study.

Similarly for the study of test drug (essential fatty acids) in rheumatoid arthritis (RA), patients of the either sex in the age group of 18 to 70 years with a diagnosis of classical or definite RA as defined by American Rheumatism Association criteria were selected.

**Inclusion criteria:**

1. Males and females within age group of 18-60 years.
2. Diagnosis of rheumatoid arthritis according to the clinical /radiological criteria's of American Rheumatism Association.
3. Patients who were willing to get enrolled in the study and gave written informed consent.

**Exclusion criteria:**

1. Patients were excluded if they had any other musculo-skeletal joint disease.
2. Patients with any known food allergies.
3. Patients with history of hypertension or any other cardiovascular disease.
4. Patients with history diabetes mellitus.
5. Patients with any other abnormal laboratory parameters
6. Patients who were taking any other nutraceutical medication/ supplements on regular basis.
7. Any patient who according to screening doctor was considered unable to comply with the study protocol.
8. Pregnant and lactating females.
9. Patients who was suffering from any other concomitant chronic condition, which could worsen during the study period necessitating removal of patient/ subject from the study.
10. Any subject / patient who was unwilling to give written informed consent.
11. Patients with prior replacement surgery or eligible for surgical intervention were not considered for inclusion in the trial.
12. Subjects/patients who were taking any other nutraceutical medication/ supplements on regular basis.
All subjects irrespective of OA or RA were on 1st line-drug therapy i.e. NSAID’s for the control of their clinical troublesome inflammatory clinical symptoms. None of them was considered severe enough to warrant second line drug therapy.

For the purpose of drug study, in total 96 patients of OA and 87 patients of rheumatoid arthritis (RA) were diagnosed taking assistance of orthopedic surgeon.

The purpose of study, study protocol and the nature of drug were explained to all the patients of both types of arthritis in their local language.

After understanding the study purpose, protocol and nature of drug, the patients who gave their willing consent in written to participate in the study were only enrolled for further study.

70 patients of OA and 70 patients of rheumatoid arthritis (RA) willingly gave the written informed consent to participate in the drug study trial.

All the patients who met the eligibility criteria’s were then randomly divided into two equal groups ‘A’ and ‘B’. Group ‘A’ served as placebo controlled group and group ‘B’ as test drug group in respective diseases, as shown below:

**Treatment groups**

**Osteoarthritis (OA):**

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo-controlled</td>
<td>35</td>
</tr>
<tr>
<td>Test-drug</td>
<td>35</td>
</tr>
</tbody>
</table>
Rheumatoid arthritis (RA):

<table>
<thead>
<tr>
<th>Group</th>
<th>No. of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo-controlled</td>
<td>35</td>
</tr>
<tr>
<td>Test-drug</td>
<td>35</td>
</tr>
</tbody>
</table>

Study Design:

A placebo-controlled, random, single blinded study design was conducted to assess and compared the anti-inflammatory activity of the test drug to placebo on inflammatory cardinal signs and symptoms in OA and rheumatoid arthritis patients. On '1st day' the inflammatory parameters were examined and recorded together with the required laboratory investigations (ESR in RA patients and LFT, RFT for both OA & RA patients) were also carried out and were labeled as base-line observations or base line values. From the 2nd day of base line observations to 43rd day (6 weeks) of treatment-period, all patients in the placebo-controlled group and test-group of OA and RA were given drug treatment as follows:

Treatment assignment

Osteoarthritis (OA):

<table>
<thead>
<tr>
<th>Group</th>
<th>Drug</th>
<th>Strength of drug</th>
<th>Dose</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo-</td>
<td>Liquid paraffin (Placebo)</td>
<td>1 ml/capsule</td>
<td>2 Cap. – t.i.d. (2 ml – t.i.d.)</td>
<td>6 weeks</td>
</tr>
<tr>
<td>Controlled</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test-group</td>
<td>LA + ALA (Test-drug)</td>
<td>150mg/Capsule</td>
<td>2 Cap. – t.i.d. (300mg – t.i.d.)</td>
<td>6 weeks</td>
</tr>
</tbody>
</table>

Abbreviation: Cap: Capsule (Soft gelatin capsule); tid.: Three times a day; LA: Linoleic acid; ALA: α-linolenic acid.
Rheumatoid arthritis (RA):

<table>
<thead>
<tr>
<th>Group</th>
<th>Drug</th>
<th>Strength of drug</th>
<th>Dose</th>
<th>Duration of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo-Controlled</td>
<td>Liquid paraffin (Placebo)</td>
<td>1 ml/capsule</td>
<td>2 Cap. – t.i.d.</td>
<td>6 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(2 ml – t.i.d.)</td>
<td></td>
</tr>
<tr>
<td>Test-group</td>
<td>LA + ALA (Test-drug)</td>
<td>150mg/Capsule</td>
<td>2 Cap. – t.i.d.</td>
<td>6 weeks</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(300mg – t.i.d.)</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviation: Cap: Capsule (Soft gelatin capsule); tid.: Three times a day;
LA: Linoleic acid; ALA: α-linolenic acid.

After 6 weeks of drug (placebo; test drug) treatment, on the 1st day of 7th week all the clinical symptoms and laboratory test parameters observed during baseline were repeated and observations were recorded. Both group patients were instructed to decrease or stop the NSAID’s only if this could be done without exacerbation of their clinical symptoms.

**Additional Instructions:**

Patients or his attendant were instructed to report immediately to investigator for any untoward outcomes or adverse reaction occurs with placebo or test-drug treatment or aggravation to their clinical symptoms by the studied drugs in between the prescribed study period.

*This study was carried out in accordance with declaration of Helsinki and principles of good clinical practice.*
Study plan for osteoarthritis and rheumatoid arthritis:

<table>
<thead>
<tr>
<th>Work up done</th>
<th>Visit 1 Screening visit</th>
<th>Visit 2 (7 days after visit 1)</th>
<th>Visit 3 For safety assessment (21 days after visit 2)</th>
<th>Visit 4 (6 weeks after visit 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete physical checkup</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Radiograph for screening/ diagnosis</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Laboratory estimation for serum lipid profile values, BT, CT, PT, RFT, LFT, ESR &amp; FBS</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Explaining of study design</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Informed written consent</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Dispensing of study drug</td>
<td>No</td>
<td>Yes Drug therapy for 21 days</td>
<td>Yes Drug therapy for 21 days</td>
<td>No</td>
</tr>
<tr>
<td>Clinical Assessment for efficacy</td>
<td>No</td>
<td>Yes (For generating baseline data)</td>
<td>No</td>
<td>Yes (Assessment for efficacy of study drug)</td>
</tr>
<tr>
<td>Safety assessment/adverse event monitoring</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Evaluation on decrease in the use of NSAIDs</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Clinical Efficacy Assessments:

- The following arthritis assessments (irrespective of OA or RA) were made at base-line and at 1st day of 7th week (i.e. after 6 weeks of study treatment period) in both group (placebo and test drug group) of OA and RA patients:
  1. Pain at rest.
  2. Pain on movement.
  3. Swelling on affected joint(s).
  4. Tenderness of joint.
  5. Duration of morning stiffness.
  6. Time to walk 50 feet just after waking up from bed in morning.
  7. Ability to perform physical activities.

- Assessments of pain, swelling, tenderness and ability for work performance were done on a '4 point' categorical scale; duration of morning stiffness and time to walk was measured in minutes as described by Jayaram S, et al. 2005 (403).

- Pain at rest as well as pain on movement was measured on a 4-point categorical scale, where 0 = absent, 1 = no interference in daily activities, 2 = some interference with daily activities and 3 = incapacitation.

- Swelling was measured on a 4-point scale where 0 = none, 1 = palpable, 2 = palpable and visible, 3 = distortion of joint centers.

- Tenderness was measured on a 4-point categorical scale

<table>
<thead>
<tr>
<th>Grade 0</th>
<th>No pain on pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Slight pain on pressure</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Pain and winching</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Patient did not allow palpitation</td>
</tr>
</tbody>
</table>
- Ability to perform physical activities (daily routine work) was graded on a 4-point scale

<table>
<thead>
<tr>
<th>Grade 0</th>
<th>No discomfort</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Some discomfort</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Discomfort and difficulty</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Not possible</td>
</tr>
</tbody>
</table>

- For parameter 1, 2, 3, 4, and 7 score grading was decided on the basis of observed change in clinical symptom by the investigator assessment and by the patient's own experienced explained to investigator in response to symptoms.

- Furthermore, the dose and number of NSAID used increased, decreased or stopped were also observed and recorded.

- Observer's opinion for degree of disease symptoms was recorded on the basis of pain score as remitted-'0'; slight or mild-'1'; moderate-'2'; and severe-'3'. [H.F.H. Hill, et al. 1979] (404).

<table>
<thead>
<tr>
<th>Grade 0</th>
<th>Remitted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Slight or mild</td>
</tr>
<tr>
<td>Grade 2</td>
<td>Moderate</td>
</tr>
<tr>
<td>Grade 3</td>
<td>Severe</td>
</tr>
</tbody>
</table>
- Therapeutic efficacy was rated on completing the trial as excellent (score-0'), good (Score-1), fair (score-2) and poor (score-3).

<table>
<thead>
<tr>
<th>Score</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Excellent</td>
</tr>
<tr>
<td>1</td>
<td>Good</td>
</tr>
<tr>
<td>2</td>
<td>Fair</td>
</tr>
<tr>
<td>3</td>
<td>Poor</td>
</tr>
</tbody>
</table>

**General Safety Assessments:**
Tolerability of the treatment at 3rd visit and 4th visit and occurrence of any adverse events with an indication of severity, duration and probability of self-medication was recorded. Additionally at these visits nausea, gastritis and loose stools were graded as 0 = absent, 1 = mild, 2 = moderate and 3 = severe.

**Laboratory Investigations:**
Blood sample was collected for the estimation of erythrocyte sedimentation rate (ESR) per hour. Moreover, the liver function test & renal function test were carried in college pathology and biochemistry laboratory as a routine course.

**Statistical Analysis:**
For individual group paired ‘t’ test was performed to find out the significance or non-significance for treatment efficacy in respective group. Whereas, un-paired student ‘t’ test was performed to find out the significance or non-significance for treatment efficacy comparison between two group treatment (placebo & test-drug treatment).
Liver Function tests in acute Viral hepatitis (non-B):  

Selection of Patients:

- The study encompassed all cases suspected clinically to be viral hepatitis and admitted to the medical wards were selected for the drug study.
- After detailed clinical examination cases like malaria, hemolytic anaemia, alcoholic liver disease and drug-induced liver disease were excluded from the study.
- The study protocol, purpose of clinical study and nature of drug was explained to all of them after their admission in wards.
- Total 40 patients showed their willingness to participate as subject in drug study; their written consent was taken.
- These 40 patients of viral hepatitis were selected for further detailed investigations like AST (SGOT), ALT (SGPT), Serum bilirubin estimation and for HBsAG positive or negative status, these were considered as base line values. Conventional treatment was started to all of them.

Study design:

- In this single blinded, randomized controlled drug study, patients were divided into two groups, group ‘A’ served as controlled-group and group ‘B’ served as test group.
- Group ‘A’ was on conventional treatment and group ‘B’ patients were given Cap. EFAs – 300 mg / t.i.d. (2 Cap./t.i.d) in addition to conventional treatment.
- Duration of study treatment was 1 week. At the end of 1 week all patients were clinically examined and investigation like AST, ALT, S. bilirubin and HbsAG were repeated.
- Comparative difference of observed changes in liver function tests in both groups were noted down.
- A lower or greater reduction of the laboratory parameters was taken into consideration as equal, non-significant or significant improvement (hepatocellular regeneration) with EFA over the controlled treatment. Then after conventional treatment was kept continue till patient’s recovery.
Inclusion criteria:
1. Males and females within age group of 18-60 years.
2. Diagnosis of acute viral hepatitis (non-B) with clinical signs and symptoms.
3. Patients who were willing to get enrolled in the study and gave written informed consent.

Exclusion criteria:
1. Patients were excluded if Hbs Ag was positive.
2. Patients with any known food allergies.
3. Patients with history of hypertension or any other cardiovascular disease.
4. Patients with history diabetes mellitus
5. Patients with any other abnormal laboratory parameters
6. Patients who were taking any other nutraceutical medication/supplements on regular basis
7. Any patient who according to screening doctor was considered unable to comply with the study protocol.
8. Pregnant and lactating females
9. Patients who was suffering from any other concomitant chronic condition, which could worsen during the study period necessitating removal of patient from the study
10. Any patient who was unwilling to give written informed consent

Study plan for viral hepatitis (non-B)

<table>
<thead>
<tr>
<th>Work up done</th>
<th>Visit 1 Screening visit</th>
<th>Visit 2 (14 days after visit 1)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening/enrollment</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Complete physical checkup</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Laboratory estimation for serum lipid profile values, BT, CT, PT, RFT, LFT, ESR &amp; FBS</td>
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<td>No</td>
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<tr>
<td>Informed written consent</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Dispensing of study drug</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Safety assessment /adverse event monitoring</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Laboratory Investigation:

- For the estimation of total bilirubin in serum, DMSO method was used using bilirubin estimation kit.

Statistical Analysis:

For individual group paired 't' test was performed to find out the significance or non-significance for treatment efficacy in respective group. Whereas, un-paired student 't' test was performed to find out the significance or non-significance for treatment efficacy comparison between two group treatment (placebo & test-drug treatment).

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