| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**CASE RECORD FORM.**

**STUDY TITLE:**
**Comparative Evaluation of Antidiabetic Activity of Acarbose, Miglitol alone and in combination with Salacia Species in patient of Type – Diabetic Mellitus.**

**STUDT DESIGN:**

Single blind, Randomized, parallel group, comparative, prospective trial.

**PROTOCOL NUMBER:**

SPONSORS ( IF ANY)

INVESTIGATOR:

## DEMOGRAPHICS

| Patients initials: ---------- | | |
|---|---|---|
| Date of birth:<br>--/ --/ -----<br>DD MM YEAR | Age:<br>(Years) ☐ | Sex (M/F): ☐ |
| Height (Cm): | Weight (kg): | |
| Informed consent form understood and singned | Yes<br>☐ | On ----------<br>(dd/mm/yyyy) |

---------- ----------

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

## INCLUSION CRITERIA:

| Sr.No | Criteria | Yes | No |
|---|---|---|---|
| 1. | | ☐ | ☐ |
| 2. | | ☐ | ☐ |
| 3. | | ☐ | ☐ |
| 4. | | ☐ | ☐ |
| 5. | | ☐ | ☐ |

**If the answer to all the above questions is "YES", then include the patient**

---------- ----------

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**EXCLUSION CRITERIA:**

| Sr.No | Criteria | Yes | No | Not applicable |
|---|---|---|---|---|
| 1. | | ☐ | ☐ | ☐ |
| 2. | | ☐ | ☐ | ☐ |
| 3. | | ☐ | ☐ | ☐ |
| 4. | | ☐ | ☐ | ☐ |
| 5. | | ☐ | ☐ | ☐ |
| 6. | | ☐ | ☐ | ☐ |
| 7. | | ☐ | ☐ | ☐ |

**If the answer to all the above questions is "NO", then include the patient**

**----------** **----------**

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**MEDICAL HISTORY (if applicable)**

| Sr.No | Long term illness | Duration | Treatment | | |
|---|---|---|---|---|---|
| | | | Completed | Under treatment | Not taken |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**SURGICAL HISTORY (if applicable)**

| Sr.No | Major surgical procedure | Indication | Duration after surgery |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**----------** **----------**

**Investigator Signature** **Date**

**Depending upon the number of visits / follow up the visit schedule should be made and may include……**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

## PHISICAL EXAMINATION (PER STUDY-SCREENING)

| General Appearance & Nutrition Status | Normal | abnormal | Not done | Comments |
|---|---|---|---|---|
| **Skin** | | | | |
| **Head, Neck & Thyroid** | | | | |
| **Lymph nodes** | | | | |
| **Eyes** | | | | |
| **Ear, Nose & Throat** | | | | |
| **Respiratory System** | | | | |
| **Cardiovascular System** | | | | |
| **Gastroinstinal system (GERD etc)** | | | | |
| **CNS** | | | | |
| **Musculoskeletal System** | | | | |
| **Others** | | | | |
| | | | | |
| | | | | |

**Are there any abnormal physical findings present? If yes, please make note of it.**

---------- ----------

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

## VITALS

| | |
|---|---|
| **Pulse rate** | **----------/ min** |
| **Respiratory** | **----------/ min** |
| **Heart rate** | **----------/ min** |
| **Temperature** | **----------/ min** |
| **Blood pressure** | **----------/ min** |

**----------** **----------**

**Investigator Signature** **Date**

## LABORATORY DATE (which ever applicable)

| Investigation | Normal values | Value reported |
|---|---|---|
| **HEMATOLOGY** | | |
| Hemoglobin | | |
| Red Blood Cell | | |
| WBC with differential count | | |
| Absolute neutrophil count | | |
| Hematocrit | | |
| Mean Corpuscular Volume (MCV) | | |
| Mean Corpuscular Volume Concentration (MCVC) | | |
| Platelets | | |
| **SERUM CHEMISTRY** | | |
| Blood Urea Nitrogen (BUN) | | |
| Creatinine | | |
| AST (SGOT) µ/l | | |
| ALT (SGPT) µ/l | | |
| Albumin | | |
| Alkaline phosphatase | | |

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

| | | |
|---|---|---|
| Total bilirubin | | |
| Bicarbonate | | |
| LDH | | |
| Glucose fasting | | |
| Glucose post prandial | | |
| Total protein | | |
| Sodium | | |
| Potassium | | |
| Calcium | | |
| Chloride | | |
| Cholesterol | | |
| Serum pregnancy test (in women of childbearing potential) | | |

**Comments on all clinical significant laboratory values outside normal range(s):**

**----------** **----------**

**Investigator Signature** **Date**

**CONCOMITANT MEDICATION (if applicable)**

**(The presence of underlying conditions or past surgeries can necessitate the use of various medications like corticosides, chemotherapy or anti-infective medications. if present, a note of the same should be made as follows).**

| Sr. No | NAME DRUG | ROUTE OF ADMINSTRATION | TOTAL DAILY DOSE | INDICATION | DURATION OF DRUG THERAPY | |
|---|---|---|---|---|---|---|
| | | | | | FROM | TO |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**Note:**

- **Brand name of the medication preferred over generic name.**
- **Enter only one medication per section. if more than one medication is used for one indication, list all of them individually in separate section.**

**----------** **----------**

**Investigator Signature** **Date**

| **Electro-Cardio Graph (ECG) (Pre-study-Screening)** | |
|---|---|
| **Date : (dd/mm/yyyy)** | **Time:** |
| **Findings:** | |
| | |
| **Investigator`s comments** | |
| | |

**----------** **----------**

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

## AE/SAE Reporting form

**Patient details:**

| | | | |
|---|---|---|---|
| Initials & other relevant identifier: (Hospital/OPD record no. etc) | | | |
| Gender: | Weight in Kg: | Date of birth (dd/mm/yyyy) | Height in cm: |

**Suspected drug(s):**

| | |
|---|---|
| Generic name of the drug | |
| Indication(s) for which suspect drug was prescribed or tested | |
| Dosage form and strength | |
| Daily dose and regimen (specify units ex. mg, ml, mg/kg) | |
| Route of administration | |
| Starting Date & time of day (dd/mm/yyyy) (am/pm) | |
| Stopping date 7 time of day (or)duration of treatment (dd/mm/yyyy) (am/pm) | |

Details of adverse event: (Mention in detail about the medical event and if possible diagnosis for that condition)

---

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

| **Expectedness:** | | |
|---|---|---|
| Expected: | Unexpected: | |
| **Intensity:** (Investigator discretion/guidelines) | | |
| Mild: | Moderate: | Severe: |
| **Assessment: :** (Investigator discretion/guidelines) | | |
| Serious: | Not–serious: | |
| **Relationship to study medication:** | | |
| Unrelated | | |
| Un likely | | |
| Possilbly | | |
| Probably | | |
| Definitely | | |
| Un known | | |
| Other attributable causes | | |
| **Other causes:** | | |
| Primary underlying disease | | |
| Study indication | | |
| Concomitant medication | | |

---------- ----------

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

| | |
|---|---|
| Study participation | |
| Other cause (Specify) | |
| **Action taken:** | |
| | |
| **Yield/out come:** | |
| Complete recovery (with out sequel) | |
| Recovered (with sequel) | |
| Ongoing | |
| Ongoing at the time of death | |

---------- ----------

**Investigator Signature** **Date**

| | |
|---|---|
| **Death:** | |
| **Unknown:** | |
| **Others (specify)** | |
| **Duration:** | |
| **Start Date: (dd/mm/yyyy)** | **Stop Date: (dd/mm/yyyy)** |
| **Details of the Investigators:** | |
| **Details of Investigators** | |
| **Name:** | |
| **Address:** | |
| **Telephone no.** | |
| **Profession:** | |
| **Signature:** | |

**----------** **----------**

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**Global Assessment:**

**Efficacy:**

Investigator

Excellent ☐ Good ☐ Poor ☐

Remarks:

---

**Efficacy:**

Patient

Excellent ☐ Good ☐ Poor ☐

Remarks:

---

**Tolerability:**

Investigator

Excellent ☐ Good ☐ Poor ☐

Remarks:

---

Patient

Excellent ☐ Good ☐ Poor ☐

Remarks:

---

---------- ----------

**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

## STUDY COMPLETION

**Study completed** ☐ **Yes** ☐ **No**

**If yes, Date of Study Completion:** --------/------/---------
**DD MM YEAR**

**If No, Date of Withdrawal:** --------/------/---------
**DD MM YEAR**

**The Reasons for Withdrawal:**

☐ No response

☐ Other illness

☐ Adverse event

☐ Lost of follow up of patient

☐ Other

☐ Death

**In case of death (if any)**
a) Date of death: _____

b) Cause of death: _____

c) Possible causal relationship with the trial: _____

**Any other comments:**
_____
_____
_____

**INVEST GATORS STATEMENT:**
**The data generated and reproduced of above is of authenticate and genuine to my knowledge.**

---------- ----------
**Investigator Signature** **Date**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

CASE RECORD FORM

**INCLUSION CRITERIA:**

**Please read carefully and tick (√) in the appropriate box**

| | Yes | No |
|---|---|---|
| A. Age: 18 years of age or older | | |
| B. Patients with Type 2 Diabetes mellitus with PPG >200 Mg/dl and $HbA_1C$ >7% | | |
| C. Patient ready to give informed consent to participate in the study after explaining about the drug and the Study | | |

**EXCLUSION CRITERIA:**

| **Please read carefully and tick (√) in the appropriate box** | **Yes** | **No** |
|---|---|---|
| A. Clinically significant deviation from normal in physical examination, laboratory parameters, ECG, as evaluated by the Clinical Investigator | | |
| B. Clinically significant coexisting diseases, including: | | |
| 1. Clinically significant cardiovascular disease, including a history of myocardial infarction. | | |
| 2. Clinically significant gastrointestinal disease, including active peptic ulcers, inflammatory bowel disease, intestinal obstruction etc. | | |
| 3. Impaired liver function/ renal function/ thyroid function tests | | |
| 4. Patients with Insulin - dependent diabetes mellitus or those who have taken insulin in the past | | |
| 5. Patients with rapidly progressive retinopathy, neuropathy, nephropathy. | | |
| C. Presence of any acute illness. | | |
| D. H/o sensitivity to study drugs i.e. Acarbose, Miglitol, Voglibose. | | |

E. History of alcohol, barbiturate, marijuana, or polydrug abuse. ☐ ☐

F. History of antidiabetic medication other than study drugs during past 3 months ☐ ☐

G. Concomitant medication affecting glucose homeostasis such as glucocorticoids within 8 weeks. ☐ ☐

H. Participation in other investigational drug studies within 8 weeks before the start of the study. ☐ ☐

I. Subjects who are unlikely to be compliant with the protocol requirements. ☐ ☐

J. Pregnant or lactating females. ☐ ☐

**PATIENT DETAILS**

**Reg. No._____** **Date: _____**

**Name: _____**

**Age: _____** **Sex: _____**

**Address:** _____

_____

**Occupation:** _____

H/o Type 2 Diabetes Mellitus since_____ years, taking following medications:

1. _____
2. _____
3. _____
4. Past h/o medical or surgical illness:

_____

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

## GENERAL EXAMINATION

| | Visit 1 | Visit 2 | Visit 3 |
|---|---|---|---|
| | __/__/__ | __/____/__ | __/____/__ |
| Temperature (deg F) | | | |
| Pulse / min | | | |
| Respiratory rate / min | | | |
| Blood pressure (mmHg) | | | |
| Heart Rate/min | | | |
| Weight (kg ) | | | |

## SYSTEMIC EXAMINATION

| | Visit 1 | Visit 2 | Visit 3 |
|---|---|---|---|
| | __/__/___ | __/____/__ | __/____/__ |
| Respiratory system | | | |
| Cardiovascular system | | | |
| Central nervous system | | | |
| Per abdomen | | | |

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**Study group:** _____

**Laboratory Investigations:**

**Hemogram:**

| | Visit 1 | Visit 2 | Visit 3 |
|---|---|---|---|
| | __/____/__ | __/____/__ | ___/____/__ |
| Hemoglobin (gm %) | | | |
| Total WBC count | | | |
| ESR (mm at end of 1 hour ) | | | |

**Blood sugar profile:**

| | Visit 1 | Visit 2 | Visit 3 |
|---|---|---|---|
| | __/____/__ | __/____/___ | __/____/___ |
| Fasting blood sugar (mg %) | | | |
| Post prandial blood sugar (mg %) | | | |
| $HbA_1C$ ( % ) | | | |

**Liver function tests:**

| | Visit 1 | Visit 2 | Visit 3 |
|---|---|---|---|
| | __/____/__ | ___/____/__ | ___/____/__ |
| SGOT (U/L) | | | |
| SGPT (U/L) | | | |
| S. bilirubin (mg %) | | | |

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**Renal function tests:**

| | Visit 1 | Visit 2 | Visit 3 |
|---|---|---|---|
| | ____/____/_ | ____/____/_ | ___/____/_ |
| S. Creatinine (mg %) | | | |

**Adverse drug reactions monitoring**

Did the patient experience any adverse event? Yes ☐ No ☐

If yes, then please fill the details as given below

| Sr.no | Adverse event (Specify) | Start date dd/mm/yy | End date dd/mm/yy | Severity* | Relation to drug** | Action taken | Out Come of the event*** |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |

*Record severity as 0- absent , 1- Mild , 2- Moderate , 3- Severe

** Grading as 0- None; 1- Remote; 2- Possible; 3- Not assessable

***Grading as 1- Resolved ; 2- Improved ; 3- Unchanged ; 4 – Worsened ; 5- Death

**Patient status**

Completed the study: YES/NO

If **NO** then,

Withdrawn before completion due to

Patient's desire : ☐

Severe side effects: ☐

Remarks: ----------

---

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**PROFORMA**

**PATIENTS NAME;**

**CONSULTANT'S NAME:**

**NAME OF HOSPITAL:**

**DATE OF ADMISSION:**

**SEX:**

**AGE:**

**WEIGHT:**

**HEIGHT:**

**BMI:**

**ADRESS:**

**CONTACT NUMBER:**

- **HOME:**
- **OFFICE:**
- **MOBILE:**

**E-MAIL:**

**OCCUPATION:**

**SOCIAL HISTORY:**

**Nonalcoholic/ Alcoholic @ the age.**

**Nonsmoker /smoker @ the age.**

**Vegetarian / non-vegetarian.**

## PHYSICAL EXAMINATION

A General Physical Examination is to done to be answer the following questions.
(Were there any abnormal physical findings present? If yes, Please make note of it in the comments)

| General Appearance & Nutrition | Yes / No | Comments |
|---|---|---|
| Skin | | |
| Head, Neck & Thyroid | | |
| Lymph nodes | | |
| Eyes | | |
| Ear, nose & throat | | |
| Respiratory System | | |
| Cardiovascular System | | |
| Abdomen | | |
| CNS | | |
| Musculoskeletal System | | |

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

Vitals (Record the vitals)

Blood Pressure SBP --------/ ------ mmHg; DBP --------/ ------ mmHg;

Pulse ----------/min

Temperature ---------- deg F

Heart Rate ---------- / min

Respiratory Rate ----------/ min

**LIST OF INVESTIGATIONS**

| **INVESTIGATION** | **Visit 1** | **Visit 2 (week 12)** | **Visit 3 (week 24)** |
|---|---|---|---|
| **1. Hb %** | | | |
| **2. TLC** | | | |
| **3. Total Bilirubin (mg/ 100ml)** | | | |
| **4. SGOT (AST) /µl** | | | |
| **5. SGPT (ALT) /µl** | | | |
| **6. Sr Creatinine** | √ | | |
| **7. Blood Pressure** | | | |
| **8. Fasting Blood Glucose** | | | |
| **9. PP Blood Glucose** | | | |
| **10 $HbA_{1C,}$** | | | |
| **11. Sr Triglycerides** | | | |
| **12. BMI** | | | |

Note : Hb% Hemoglobin; TLC=Total Leucocyte Count; SGOT=Glutamy1 Oxalo Transferase; SGPT=Serum Glutamy1 Phosphory1 Transferase; PP=Post prandial BMI =Body mass index

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**ON EXAMINATION:**

| **Sr. No.** | **Date** | **Time** | **Blood glucose level** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**PAST MEDICAL HISTORY:**

**PAST MEDICATION HISTORY:**

**PRESENT COMPLAINTS:**

**DIAAGNOSTIC TESTS PERFORMED:**

| **Sr. NO.** | **Date** | **Test** | **Normal range** | **Observed value.** |
|---|---|---|---|---|
| **1** | | | | |

**OTHER TESTS PERFORMED:**

| CRF | Protocol number |
|---|---|
| ENROLLMENT NUMBER: | PATIENTS INITIALS: |

**MEDICATION DETAILS:**

| **Sr. no.** | **Medication** | **Compositions** | **Dose and Frequency** | **Rout** | **Date** |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

**COMMENTS:**

**DATE:**