Clinical Research Submission

Last Modified: 14/7/2025, 11:20:23 am

1. Administration

Name of Research Principal: Manisha
Department: CP & T
Study Title: A Comparative Study of the effects of Telmisartan versus Losartan on Blood Glucose and Lipid Profile in Adult Patients with Stage 1 Hypertension attending a Teaching Hospital
Review Requested: Full Committee Review
Submission Date: 14/7/2025
Submitted At: 14/7/2025, 4:42:48 am
Version Number: 01
Date: 11/12/2020
Protocol Number: 01
Employee code: 331010051162
Summary:
Selected Elements:
Other Reason:

2. Investigators

Researchers

Name: Dr. P Usha Rani
Designation: Professor & HOD
Qualification: Medical Postgraduation, Superspeciality
Department: CP & T
Investigator Type: hod
Alternate Gmail: drsroopali@gmail.com
Contact: 9036619259

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Name: Manisha
Designation: Senior Resident
Qualification: Medical Postgraduatiom
Department: CP & T
Investigator Type: Principal Investigator
Alternate Gmail: manisha.0419@gmail.com
Contact: 9573784725

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Name: Dr. Roopali
Designation: Assistant Professor
Qualification: Medical Postgraduation, Superspeciality
Department: CP & T
Investigator Type: Guide
Alternate Gmail: nilap5.0@gmail.com
Contact: 9036619259

Funding Details

Funding Source: self-funding
Total Estimated Budget: ₹ 1000
Proposed Budget: ₹ 1000
Cost Per Patient: ₹ 100
Total Project Cost: ₹ 1000
NIMS Investigations:

- **Name:** CBP
  Cost: 5

Is Outsourced: Yes
Outsourced Investigations:

- **Name:**
  Cost:
  Lab:
  NABL:

false false

Overview of the Research

Summary: To study the effect of Telmisartan and Losartan on Blood Glucose and Lipid Profile in adult stage 1 hypertensive patients.
Type of Study: case-control
Other Study Type: null
External Laboratory Involved: No
Specify (if External Lab):
Justification: estimated using a previous study depending on the mean change in LDL in the telmisartan group from baseline to end of study, and also considering the loss to follow up and dropout cases, the obtained calculated sample size was rounded off to 100
Sample Size: 100
Employee code: 331010051162

Participants

Type of Participants: patient
Specify (if applicable): N/A
Justification:
Additional Safeguards:
Reimbursement Details:
Advertisement Details:
Payment Type: No
Advertisement Type: No
Employee code: 331010051162
Vulnerable Groups:

Benefits Details

Reimbursement Details:
Risk Management Strategy:
Anticipated Type of Benefits: No
Participant Benefits: Indirect
Society Benefits: Direct
Improvement Benefits: Direct
Employee code: 331010051162

Consent Details

Seeking Waiver of Consent Type: No
Specify:
Employee code: 331010051162
Version Number: 01
Date: 12/12/2020
Subject: No
Certificates: No
Selected Languages: Telugu, Urdu
Telugu
Version: 01
Date: 12/12/2020
,
Urdu
Version: 01
Date: 12/12/2020
PIS Selected Items:

- Statement that study involves research & explain purpose of research
- Statement that consent & participation are voluntary
- Expected Risks and benefits to the study subject
- Alternatives procedures / therapies available
- Contact information of PI and Member Secretary of EC
- Financial compensation and medical management in SAE
- Right to withdraw from study at any time
- Expected duration of participation
- Maintenance of Confidentiality
- Description of procedures to be followed, treatment schedule and probability of random assignment
- Responsibility of subject

Summary:
Waiver Selected Elements:

Compensation & Payment Details

Waiver of Consent Type: No
Specify:
Compensation for Research-Related Injury: Yes

Specific Compensation Details: calculated as per NDCT rules
Employee code: 331010051162

Storage and Access Details

Control Details:
Access Details:
Sample Access Type: Yes
Sample Details: Identifiable
Document Access Type: NA
Drugs Access Type: NA
Employee code: 331010051162
null

Additional Support Information

Support Type: No
Additional Details:
Employee code: 331010051162

Declaration

Selected Declarations:

- • I/We certify that the information provided in this application is complete and correct.
- • I/We confirm that all investigators have approved the submitted version of proposal /related documents
- • I/We confirm that this study will be conducted in accordance with the latest ICMR National Ethical Guidelines for Biomedical and Health Research involving HumanParticipants and other applicable regulations and guidelines including responsible
- • I/We will comply with all policies and guidelines of the institute and affiliated / collaborating institutions wherever applicable
- • I/We confirm that we shall submit any protocol amendments, adverse events report,significant deviations from protocols, regular progress reports and a final report and also participate in any audit of the study if needed

- • I/We confirm that we will maintain accurate and complete records of all aspects of the study.
- • I/We will protect the privacy of participants and assure safety and confidentiality of study data and biological samples.

Principal Investigator: Dr. Manisha
Date: 14/7/2025
Signature: Dr. Manisha
<>
Co-PI / Guide: Dr. Roopali
Date: 14/7/2025
Signature: Dr. Roopali
<>
HOD: Dr. P. Usha Rani
Date: 14/7/2025
Signature: Dr. P. Usha Rani

14. Checklist

MOU between collaborating partners	File: null
Participant Information Sheet (PIS) and Informed Consent Form (ICF)	View File
Advertisement / material to recruit participants	File: null
Assent form for minors (12-18 years)	File: null
CRF / Interview guides / Focused Group Discussions (English and translated)	View File
EC clearance of other centers	File: null
Cover letter enlisting all documents enclosed	View File
Good Clinical Practice (GCP) training of investigators in last 3 years	View File
Copy of the detailed protocol (clearly identified numbered and dated) and synopsis	View File
Brief CV of all Investigators (updated, signed and dated)	View File

Insurance policy / participant coverage details File: null