

Clinical Research Submission

Last Modified: 14/7/2025, 11:16:51 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 Postgraduation
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

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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

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Co-PI / Guide: Dr. Roopali

Date: 14/7/2025

Signature: Dr. Roopali






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HOD: Dr. P. Usha Rani

Date: 14/7/2025

Signature: Dr. P. Usha Rani

14. Checklist

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

**Good Clinical Practice (GCP) training of
investigators in last 3 years**



[View File](#)