Clinical Research Submission

Last Modified: 7/11/2025, 3:53:02 PM

1. Administration

Name of Research Principal: Roopali somani
Department: Clinical Pharmacology & therapeutics
Study Title: Evaluation of Drug interaction between Levetiracetam and High dose Methotrexate in primary central nervous system Lymphoma: A Retrospective cohort study
Review Requested: Full Committee Review
Submission Date: 7/11/2025
Submitted At: 7/7/2025, 8:50:09 AM
Version Number: 01
Date: 6/24/2025
Protocol Number: CPT/LVT/01
Employee code: 51046
Summary:
Selected Elements:
Other Reason:

2. Investigators

Researchers

Name: Roopali Somani
Designation: Assistant Professor
Qualification: DM Clinical Pharmacology
Department: Clinical Pharmacology & therapeutics
Investigator Type: Principal Investigator
Alternate Gmail: drsroopali@gmail.com
Contact: 9036619259
,

Name: Dr. P Usharani
Designation: Senior Prof and Head
Qualification: DNB
Department: Clinical Pharmacology & Therapeutics
Investigator Type: hod
Alternate Gmail: ushapingali@yahoo.com
Contact: 9849574143
,
Name: Dr. Meher lakshmi
Designation: Additional professor
Qualification: DM Medical Oncology
Department: Medical Oncology
Investigator Type: Co-investigator
Alternate Gmail: drsroopali@gmail.com
Contact: 9036619259

Funding Details

Funding Source: self-funding
Total Estimated Budget: ₹ 5000
Proposed Budget: ₹ 5000
Cost Per Patient: ₹ 100
Total Project Cost: ₹ 5000
NIMS Investigations:

- **Name:** nil
  Cost: 0

Is Outsourced: Yes
Outsourced Investigations:

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

false false

Overview of the Research

Summary: This retrospective cohort study investigates whether levetiracetam affects methotrexate elimination and toxicity when co-administered in CNS lymphoma patients undergoing HDMTX therapy. Data will be retrieved from patients case records in the department of medical oncology and lab details from department of Clinical Pharmacology. Patients receiving multiple cycles of HDMTX will be included in the study multiple times (once after every MTX infusion). Time to non-toxic MTX concentration , defined as hours between the end of MTX infusion to MTX serum concentrations 24 value < 10 µmol/L, 48hours

Type of Study: retrospective

Other Study Type: null

External Laboratory Involved: No

Specify (if External Lab):

Justification: Assuming 40% patients in group A have 24h MTX ≥10 µg/mL and 10% in group B, which is 30% absolute difference between the groups, with confidence of 95% and power = 80%, required sample size is 28 patients per group. Total sample size of 56 patients

Sample Size: 56

Employee code: 51046

Participants

Type of Participants: patient

Specify (if applicable): N/A

Justification:

Additional Safeguards:

Reimbursement Details:

Advertisement Details:

Payment Type: NA

Advertisement Type: No

Employee code: 51046

Vulnerable Groups:

Benefits Details

Reimbursement Details:

Risk Management Strategy:

Anticipated Type of Benefits: NA
Participant Benefits: Indirect
Society Benefits: Indirect
Improvement Benefits: Direct
Employee code: 51046

Consent Details

Seeking Waiver of Consent Type: Yes
Specify:
Employee code: 51046
Version Number:
Date: 7/7/2025
Subject:
Certificates:
Selected Languages:
PIS Selected Items:
Summary: no
Waiver Selected Elements:

- retrospective studies, where the participants are de-identified or cannot be contacted

Compensation & Payment Details

Waiver of Consent Type: No
Specify:
Compensation for Research-Related Injury: No
Specific Compensation Details:
Employee code: 51046

Storage and Access Details

Control Details: study documents will be stored under lock and key
Access Details:
Sample Access Type: Yes
Sample Details: Unidentified
Document Access Type: Yes
Drugs Access Type: NA

Employee code: 51046
null

Additional Support Information

Support Type: No
Additional Details:
Employee code: 51046

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: Roopali Somani
Date: 7/6/2025
Signature: roopali
<>
Co-Investigator 1: Dr.Meher Lakshmi Konatam
Date: 7/6/2025
Signature: Meher Lakshmi
<>

HOD: Dr. P Usharani
Date: 7/6/2025
Signature: usharani

14. Checklist

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