Clinical Research Submission

Last Modified: 7/11/2025, 3:57:33 PM

1. Administration

Name:	Roopali Somani
Department:	CPT
Submission Date:	7/8/2025
Review Type:	Full Committee Review
Study Title:	tofacitinib in JIA population
Short Title:	
Protocol:	tof/cpt/01
Version:	01
Date:	2025-06-09T18:30:00.000Z

2. Investigators

Type:	principal
Name:	Roopali Somani
Designation:	Assistant professor
Qualification:	DM
Department:	Department of Clinical Pharmacology
Email:	drsroopali@gmail.com
Contact:	9036619259

Type:	hod
Name:	Dr. P usharani
Designation:	Senior Prof & Head
Qualification:	DNB

Department:	Department of Clinical Pharmacology
Email:	usharanipingali@yahoo.com
Contact:	9849574143

3. Investigators Count

PI Count:	01
Co-PI Count:	02
Duration:	13 months

4. Funding Details

Estimated Budget: 5 lakh only
Funding Source: Pharmaceutical Industry sponsored
false
Sponsor Name: Hetero Drugs
Sponsor PAN: trcbvgj
Sponsor GST: adgjhakjdlkj
Total Grant: ₹ 25 lakh
Budget Items:

- **Per completed patients total sponsor grant:** 2 lakh
- **Per completed patients manpower sponsor grant (PI, Co-PI, coordinator, others):** 3 lakh
- **Per completed patients overhead:** 1lakh
- **Startup fee:** 20000
- **Archival fee:** 25000

NIMS Investigations:

- **Name:** cbc
  Cost: 100
- **Name:** RFT
  Cost: 200
- **Name:** LFT
  Cost: 200
- **Name:** HBa1c

Cost: 350

- **Name:** Lipid profile
  Cost: 400

Personnel:

- **Designation:** co-ordinator
  Fees: 5000
- **Designation:** Data Entry Operator
  Fees: 1000

Is Outsourced: Yes
Outsourced Investigations:

- **Name:** HsCRP
  Lab: VIjaya Diagnostic
  NABL: Yes

5. Overview Research

Summary: This is a randomized withdrawal, double blind, placebo controlled study of pediatric subjects (2 to <18 years of age) with JIA. The primary objective is to compare the efficacy of tofacitinib versus placebo for the treatment of signs and symptoms of JIA at Week 26 of the double blind phase as measured by the percentage of subjects with disease flare (according to PRCSG/PRINTO Disease Flare criteria) after Week 18 of the open label run in phase.All eligible subjects enrolled in the study will initially receive open label tofacitinib for 18 weeks (run in phase). At the end of the 18 week run in phase, only subjects who achieve at least a JIA ACR 30 response will be randomized to the 26 week double blind, placebo controlled phase. Subjects who do not achieve a JIA ACR 30 response at this time point will be discontinued from the study. In addition, subjects who experience a single episode of disease flare at any time during the study (including the open label run in and double blind phase) will also be discontinued from the study. All subjects participating in this study, including those discontinued from the study, will have the option, if eligible (based on inclusion and exclusion criteria), of enrolling in the tofacitinib JIA long term extension study (A3921145).
Study Type: Regulatory clinical trials
Other Type:

6. Methodology

Sample Size:	120
Participants per Site:	50
Lab Outsourcing:	Yes
Lab Details:	Vijaya Diagnostic

7. Participants

Type:	Patient
Vulnerable Groups:	
Other Participant:	
Reimbursement:	Yes
Details:	10000 per patient at every visit
Additional Safeguards:	
Justification:	

8. Benefits

Any Risk:	Yes
Risk Details:	risk of adverse events due to the drug
Risk Strategy:	baseline and every 4 weeks blood counts will be monitored. if there is any decrease in counts below predefined limits in protocol then patient will be withdrawn from study
Participant Benefits:	Direct
Social Benefits:	Direct
Scientific Benefits:	Direct

9. Consent

Waiver Consent:	No

Translated Languages:	Telugu
Other Reason:	

10. Payment

Injury Treatment:	Yes
SAE Compensation:	Yes

11. Storage

Docs Control:	Yes
Drugs Control:	Yes

12. Additional Info

Any Additional:	No
Details:	

13. Declaration

- 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 NDCT RULES, ICMR National Ethical Guidelines for Biomedical and Health Research involving Human Participants and other applicable regulatory guidelines.
- I/We will comply with all policies and guidelines of the institute and affiliated / collaborating institutions wherever applicable.
- I/We will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the EC approved protocol.

- I/We declare that the expenditure in case of injury related to the study will be taken care of.
- I/We agree to inform all trial subject, that the drugs are being used for investigational purposes.
- I/we ensure that the requirements relating to obtaining informed consent and ethics committee review and approval specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met.
- I/We confirm that we shall submit any protocol amendments, serious 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.
- I/We hereby declare that I / any of the investigators, researchers and / or close relative(s), have no conflict of interest (Financial / Non-Financial) with the sponsor(s) and outcome of study.
- If Conflict of interest is present, kindly declare and specify details
- I/We declare / confirm that all necessary regulatory approvals will be obtained as per requirements wherever applicable.

Principal Investigator

Name: Roopali Somani
Signature: roopali
Date: N/A

Guide

Name:
Signature:
Date: N/A

Head of Department

Name:
Signature:
Date: N/A

Co-Investigator 1

Name:

Signature:
Date: N/A

Co-Investigator 2

Name:
Signature:
Date: N/A

14. Checklist

Cover letter	📎 View File
Brief CV of all Investigators- Updated, signed and dated	📎 View File
Good Clinical Practice (GCP) training of investigators in last 3 years	📎 View File
EC clearance of other centers	File: null
Agreement between collaborating partners	File: null
MTA between collaborating partners	File: null
Insurance policy / certificate	📎 View File
Copy of CTA signed with the sponsor	📎 View File
Provide all significant previous decisions (e.g. those leading to a negative decision or modified protocol) by other ECs / Regulatory authorities for proposed study (whether in same location or elsewhere) and modification(s) to protocol	File: null
Copy of the detailed protocol (clearly identified numbered and dated) and synopsis (summary as far as possible in non-technical language, flowchart, diagrammatic representation of the protocol)	📎 View File
Investigators Brochure (If applicable for drug / biologicals / device trials)	📎 View File
Participant Information Sheet (PIS) and Informed Consent Form (ICF) (English and translated)	📎 View File

with version number and dated	
Assent form for minors (12-18 years) (English and Translated)	File: null
Proforma / Questionnaire / Case Report Forms (CRF) / Interview guides / Guides for Focused Group Discussions (FGDs) (English and translated)	📎 View File
Advertisement / material to recruit participants (fliers, posters, etc.)	File: null
DCGI Approval letter	📎 View File
Others specify	File: null