Tata Medical Center

14, Major Arterial Road (EW)
New Town, Rajarhat
Kolkata – 700 160

Tel.: +91 33 6605 7577; **E Mail**: info@tmckolkata.com
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To,
The Chairman,
Institutional Review Board,
Tata Medical Center,
14, MAR (EW), New Town, Rajarhat,
Kolkata 700160

Dated: 03, September 2026

Subject: Request for Initial Study Submission to IRB

Dear Sir/Madam,

We are submitting IRB Documentation for the study entitled **"A Multicenter Asparaginase Monitoring Study in patients with newly diagnosed Acute Lymphoblastic Leukemia (ALL)**"

This is a prospective, multi-centre, observational study to assess the pharmacokinetic characteristics of different brands of pegylated E. coli asparaginase biogenerics in newly diagnosed patients with acute lymphoblastic leukemia (ALL) in India during the entire intensive phase of chemotherapy. L-asparaginase is an effective chemotherapeutic agent for the treatment of patients suffering from ALL. Native L-asparaginase is associated with high incidence of clinical hypersensitivity (immunogenicity) and is required to be administered in multiple doses. This requires multiple visits to the hospital which is inconvenient to patients.
Pegaspargase (a pegylated L-asparaginase), on the other hand, has a lower incidence of immunogenicity compared to L-asparaginase. Moreover, it has a longer plasma half-life due to which 1-2 injections are sufficient in the induction phase of chemotherapy based on patient's risk stratification. The convenient dosing along with lower incidence of toxicity makes pegaspargase safer and more efficacious for treating ALL. The purpose of this study is to assess the pharmacokinetic characteristics of different brands of pegaspargase when administered to patient with newly diagnosed ALL during the treatment phases, using the institutional chemotherapy protocol.

Primary Objectives:

- To evaluate the pharmacological efficacy of different PEG Asparaginase biogenerics administered to patients with ALL across India, determined by serial therapeutic drug monitoring of plasma asparaginase activity levels.

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Secondary Objectives:

- To monitor asparaginase activity serially post each dose of PEG Asparaginase till the end of treatment.
- To assess the presence of anti-asparaginase antibodies in patients showing silent inactivation.

Expected Study Outcomes:

- Efficacy of Biogeneric Formulations:
  Assessment of the pharmacokinetic efficacy of different PEG-asparaginase biogenerics by evaluating trough activity levels and capturing instances of silent inactivation—defined as a trough plasma asparaginase activity level <100 IU/L at Day 14 ± 2 post-dose in the absolute absence of clinical hypersensitivity.

- Pharmacokinetic (PK) Outcome:
  Trough Serum Asparaginase Activity: The mean or median asparaginase activity level measured at the trough time-point (Day 14 ± 2 post-dose) during the entire treatment phase.

- Therapeutic drug monitoring platform:
  Developing a systematic drug monitoring platform in the participating centers by providing the knowledge base.

We have therefore submitted to the IRB for consideration as an initial study procedure. Please accept the essential documents as needed by the IRB for processing.

Yours faithfully,

Recoverable Signature

X

Dr. Shivam Bansal
Principal Investigator
Signed by: 8163b6dc-a91b-4133-b344-624b80a78776

Dr. Shivam Bansal
Principal Investigator

03/Sep/2026

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I, acknowledge the receipt of above-mentioned document(s) on behalf of the Ethics Committee

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Date Received	**Signature**	**Name of the Personnel**