

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2024/008**

Scientific title of trial: **A Multicentre, open-labelled randomized controlled trial to evaluate the efficacy and safety of therapeutic plasma exchange in subjects with snakebite associated thrombotic microangiopathy compared to those receiving standard care alone.**

Date of commencement (enrolment of first participant): **Trial started on 1st September 2024. No patients have been admitted to NHSL, Colombo yet.**

Progression: 6 months ☐ **1 year** ☒ ☐ 2 years ☐ 3 years ☐
At completion ☐

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: **Yes**
The following section was added to Patient Randomization section of the protocol and information sheet as recommended by the Ethics Review Committee of the Faculty of Medicine, University of Colombo.

Statement added: "Withdrawing of a patient from the trial after recruitment: After patient recruitment, during the intervention period, in the event the treating physician feels that introducing OR omitting plasma exchange (as may be the case according to the treatment arm) will be beneficial to the patient, this will be allowed and the patient will come off trial and this will be considered an endpoint."

Any changes to trial outcomes after commencement: **No**

2. Current status

Recruitment status: pending/ **recruiting**/ recruitment complete: follow up continuing/ recruitment complete: follow up complete/ recruitment suspended / recruitment terminated

Number assessed for eligibility:

Number recruited and allocated/randomized: **13**

Number allocated/randomized to each intervention/arm (please edit as relevant):

Arm 1: Control arm - **08**

Arm 2: Treatment arm - **05**

Losses/exclusions after allocation/randomization (please edit as relevant):

Arm 1: **None**

Arm 2: **None**

3. Trial output

Date of trial completion ("last patient, last visit"): **Ongoing trial**

Final sample size: **Expected sample size in 140 at the end of the trial in 2 years (Year 2026).**

Summary of Interim/Final data (if available):

No data analysis yet.

Abstract presentations of results at scientific meetings

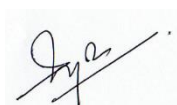
Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
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Professor Eranga Wijewickrama

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Name and signature of Responsible Registrant/
Principal Investigator

Date: 15th September 2025