

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: [SLCTR/2025/024](#)

Scientific title of trial: [A double-blind randomized controlled trial of the feasibility and acceptability of folic acid supplementation in reducing depression and suicidal behaviour: A pilot study](#)

Date of commencement (enrolment of first participant): [Commencement pending](#)

Progression: 6 months ☐ 1 year ☒ 2 years ☐ 3 years ☐

At completion ☐

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: [None](#)

Any changes to trial outcomes after commencement: [Commencement pending](#).

This progress report covers the first twelve months of the project, representing the initial preparatory phase. Despite the study being a Phase IV trial, the NMRA, following a review of the study protocol, specified that completion of NMRA registration is a mandatory requirement. Therefore, the team focused primarily on completing the NMRA registration process, which is essential for initiating the study. During this period of twelve months, the team focused on fulfilling all regulatory requirements, notably submitting the documents for the NMRA registration process. Following the initial submission, comments and feedback were received from NMRA. The team is currently addressing these comments and undertaking the required revisions to the submitted documents. Additional time will be needed to complete the required revisions before resubmission. As these foundational regulatory activities were ongoing, the commencement of the study, along with the patient recruitment and other related study procedures, was not feasible within this reporting period.

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: [Eligibility assessment remains pending](#)

Number recruited and allocated/randomized: [pending](#)

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

Arm 1: [pending](#)

Arm 2: [pending](#)

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

Arm 1: pending

Arm 2: pending

3. Trial output

Date of trial completion ("last patient, last visit"): Not yet available

Final sample size: Not yet available

Summary of Interim/Final data (if available):

Not yet available

Abstract presentations of results at scientific meetings

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

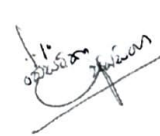
Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
No abstracts have been produced yet.	None

Publications

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

Title of paper	Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)
No papers have been produced yet.	None


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Date: 2026.06.23