

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2017/030

Scientific title of trial: An investigator initiated and conducted, multicentre, international, double-blinded, placebo-controlled, parallel-group, randomised controlled trial to determine the effect of more intensive blood pressure control provided by a fixed low-dose combination blood pressure lowering pill ("Triple Pill") strategy on top of standard of care, on time to first occurrence of recurrent stroke in patients with a history of acute stroke due to intracerebral hemorrhage

Date of commencement (enrolment of first participant): The first subject was randomized on 17 Oct 2017 at site 94024 - Kurunegala Teaching Hospital

Progression: 6 months 1 year 2 years 4 years
At completion

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes. Protocol amendment version 4.0 dated 29 April 2020.

Any changes to trial outcomes after commencement: None.

2. Current status

Recruitment status: recruiting

Number assessed for eligibility: 711

Number recruited and allocated/randomized: 525

Number allocated/randomized to each intervention/arm (please edit as relevant): Data not available for each arm as study is double blind. The randomization ratio will be 1:1 Triple Pill vs. Placebo 1:1

Arm 1:

Arm 2:

Losses/exclusions after allocation/randomization (please edit as relevant): Data not available for each arm as study is double blind. Total number of losses- 45 (After randomization) Total death - 18, Lost to follow-up - 3, Consent withdrawals - 24

Arm 1:

Arm 2:

3. Trial output

Date of trial completion ("last patient, last visit"): 30th June 2024

Final sample size: 1500

Summary of Interim/Final data (if available):

Not applicable

Abstract presentations of results at scientific meetings

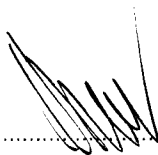
Note: please include a URL link or scanned copy of the abstract

Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).
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)
None	



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Dr. Bimsara Senanayake
Principal Investigator

Date: