

## Progress Report: Sri Lanka Clinical Trials Registry

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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 haemorrhage

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                      3 years  
                  4 years                      5 years                      6 years                      7 years **X**  
                  At completion

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### 1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes.  
Protocol amendment version 6.0 dated 06 Dec 2022

Any changes to trial outcomes after commencement: None

### 2. Current status

Recruitment status: recruiting

Number assessed for eligibility: 1521

Number recruited and allocated/randomized: 1096

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-118 (After randomization) Total death -90, Lost to follow-up -13, Consent withdrawals - 25

Arm 1:

Arm 2:

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### 3. Trial output

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

Final sample size:

Summary of Interim/Final data (if available):

N/A
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Abstract presentations of results at scientific meetings

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

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

Publications

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

<b>Title of paper</b>	<b>Full citation (please include authors, title of journal, volume, issue and page numbers, and/or DOI)</b>
Triple Therapy Prevention of Recurrent Intracerebral Disease Events Trial: Rationale, design and progress	Anderson CS, Rodgers A, de Silva HA, et al. Triple Therapy Prevention of Recurrent Intracerebral Disease Events Trial: Rationale, design and progress. International Journal of Stroke. 2022;17(10):1156-1162. doi:10.1177/17474930211068671



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Name and signature of Responsible Registrant/  
Principal Investigator

Date: 20 Sep 2024