

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: [SLCTR/2024/014](#)

Scientific title of trial: [Isobaric Bupivacaine versus Hyperbaric Bupivacaine for Spinal Anaesthesia in Caesarean sections: Prospective Randomized clinical trial.](#)

Date of commencement (enrolment of first participant): [28th November 2024.](#)

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

At completion ☐

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement:

- [Sample size changed from 152 to 158 \(152 is the required total minimal sample size\)](#)

Any changes to trial outcomes after commencement: [No changes to primary or secondary outcome.](#)

2. Current status

Recruitment status: [recruitment completed](#)

Number assessed for eligibility: [Approximately 180](#)

Number recruited and allocated/randomized: [158](#)

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

Arm 1: [\(hyperbaric\)-79](#)

Arm 2: [\(isobaric\)-79](#)

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

Arm 1: [13 participants excluded from heart rate change and blood pressure change analysis due to incomplete data.](#)

Arm 2: [5 participants excluded from heart rate change analysis due to incomplete data.](#)

3. Trial output

Date of trial completion ("last patient, last visit"): [28th February 2025](#)

Final sample size: 158 participants

Summary of Interim/Final data (if available):

Preliminary results suggest that there is significant efficacy and safety in hyperbaric bupivacaine compared to isobaric bupivacaine. Full analysis is pending.

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 yet	

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 yet	

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Name and signature of Responsible Registrant/
Principal Investigator

Date: 03/06/2025