

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2024/019

Scientific title of trial: TREATment of Lower Respiratory Tract Infection in Selected Hospitals in Southern Sri Lanka. (A stepped-wedge cluster randomized trial of an electronic clinical decision support tool (eCDST) for the diagnosis and treatment of lower respiratory tract infection (LRTI) in Southern Sri Lanka)

Date of commencement (enrolment of first participant): The trial has not yet commenced, as we are still working on blanket approval from the Education, Training, and Research Unit, Ministry of Health, Sri Lanka. The patient enrollment set to begin once approval is received.

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

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: The trial has not yet commenced. The ERC approved protocol amendments were submitted to the SLCTR in November, 2024. They have now been updated on the SLCTR website.

Any changes to trial outcomes after commencement: The trial has not yet commenced. The ERC approved amendments of trial outcomes were submitted to the SLCTR in November, 2024. They have now been updated on the SLCTR website.

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:

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

Arm 1:

Arm 2:

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

Arm 1:

Arm 2:

3. Trial output

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

Final sample size:

Summary of Interim/Final data (if available):

After receiving initial SLCTR approval in May 2024, we submitted protocol amendments to the SLCTR, which have been approved. The changes have been updated on the website. Patient enrolment is scheduled to begin once approval is received from the Education, Training and Research Unit, Ministry of Health, Sri Lanka.

Abstract presentations of results at scientific meetings

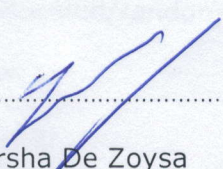
Note: please include a URL link or scanned copy of the abstract

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

Publications

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Dr. Warsha De Zoysa
Name and signature of Responsible Registrant/
Principal Investigator

Date: 03/06/2025