

## Progress Report: Sri Lanka Clinical Trials Registry

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SLCTR registration number: **SLCTR/2017/024**

Scientific title of trial: 25/9/2017

Date of commencement (enrolment of first participant): 2

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

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### 1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: None

Any changes to trial outcomes after commencement: None

### 2. Current status

Recruitment status: pending/ **recruiting**/ recruitment complete/ recruitment suspended / recruitment terminated

**Note:** We had to suspend the trial from 03/2018 to 11/2018 due to lack of suitable staff to conduct the trial.

Number assessed for eligibility: over 300

Number recruited and allocated/randomized: 154

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

Arm 1: 77

Arm 2: 77

Losses/exclusions after allocation/randomization (please edit as relevant): 34

Arm 1:

Arm 2:

### 3. Trial output

Date of trial completion ("last patient, last visit"): not applicable as yet

Final sample size: 280

Summary of Interim/Final data (if available):

Study is currently ongoing. We have planned for an interim analysis when 140 patients are recruited (currently 154 recruited). The clinical and laboratory data is being entered for the interim analysis.

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>

Publications

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

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Name and signature of Responsible Registrant/  
Principal Investigator

Date: 30/01/2019