

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2021/002

Scientific title of trial: Randomized Double-Blind Phase II Clinical Trial to Assess the Efficacy and Safety of an Ayurvedic Formulation, in COVID-19 Infected Patients

Date of commencement (enrolment of first participant): 2021-01-08

Progression: At completion

1. Baseline data

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

Trial was extended to three more sites: 1. Neville Fernando Teaching Hospital, 2. University Hospital of Kothalawala Defence University and 3. Divisional Hospital, Hikkaduwa

Any changes to trial outcomes after commencement: None.

2. Current status

Recruitment status: recruitment complete: follow up complete.

Number assessed for eligibility: 980

Number recruited and allocated/randomized: 200

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

Arm 1: 100

Arm 2: 100

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

Arm 1:12

Arm 2:17

3. Trial output

Date of trial completion ("last patient, last visit"): 2021/09/13

Final sample size: 171

Summary of Interim/Final data (if available):

Not available yet. Data analysis and manuscript preparation for publishing results of the trial is in progress.
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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

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)



Dr. Ananda Wijewickrama.

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Name and signature of Responsible Registrant/
Principal Investigator

Date: 29.06.22.