

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: **SLCTR/2021/030**

Scientific title of trial: **Phase 1 clinical trial to determine safety of a herbal formulation Link Livecare™ in healthy human volunteers**

Date of commencement (enrolment of first participant): **28/02/2022**

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

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: **Yes; removal of liver fibro scanner as an investigation to ensure normal liver function in recruiting volunteers.**

Any changes to trial outcomes after commencement: **No**

2. Current status

Recruitment status: **recruitment complete: follow up continuing**

Number assessed for eligibility: **56**

Number recruited and allocated/randomized: **28**

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

Losses/exclusions after allocation/randomization (please edit as relevant): **7**

3. Trial output

Date of trial completion ("last patient, last visit"): **last visit (23/09/2022)**

Final sample size: **21**

Summary of Interim/Final data (if available):

Interim Data has been forwarded to the DSMB and no safety concerns regarding the test medication has been reported

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).
N/A	N/A
N/A	N/A

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)
N/A	N/A
N/A	N/A

Professor Colin Goonewardena

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Name and signature of Responsible Registrant/
Principal Investigator

Date: *27/10/22.*