

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2018/012

Scientific title of trial: Effect of a standardized herbal drug of *Coccinia grandis* (L.) Voigt on metabolic profile in patients with type 2 diabetic mellitus

Date of commencement (enrolment of first participant): 06.03.2019

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

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~~

Number assessed for eligibility: 48

Number recruited and allocated/randomized: 15

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

Arm 1: 8 (Placebo)

Arm 2: 7 (Test)

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

Arm 1: No

Arm 2: No

- Placebo and herbal drugs were prepared and standardized. Patients were enrolled for the clinical trial based on the inclusion and exclusion criteria defined in the proposal. Herbal and placebo drugs were given for them according to a random number table. The routine medical check-up was continued 2 weeks after the recommendation of herbal and placebo drugs. The selected biochemical parameters such as serum concentration of γ -GT, ALT, AST, ALP, creatinine, fasting plasma glucose concentration, % of HbA_{1C} and lipid profile were estimated on collected blood samples from recruited diabetic patients.

3. Trial output

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

Final sample size: N/A

Summary of Interim/Final data (if available): No

None

Abstract presentations of results at scientific meetings None
Note: please include a URL link or scanned copy of the abstract

Publications None
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 A.P. Attanayake



Name and signature of Responsible Registrant/
Principal Investigator

Date: 20/5/2019