

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/ 2016/ 007

Scientific title of trial: "SUPPLEMENT EFFECT OF CHERUKURINJA (Gymnema lectiferum) ON GLYCEMIC CONTROL AND ON SELECTED BIOCHEMICAL AND PHYSIOLOGICAL PARAMATERS AMONG PATIENTS WITH TYPE II DIABETES MILLITUS"

Date of commencement (enrolment of first participant):16/10/2019

Progression: 6 months 1 year 2 years 3 years

At completion

1. Baseline data

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

320 Patient collection was completed, details of the patients were entered in the CR Form, all the details of the research process was explained and informed consent form was signed by the patient and the principal Investigator during the period from 15/10/2019 to14/02/2020. Clinical work and basic investigations could not able to be started immediately on the previously collected patients due to the covid 19 pandemic situation in the country and in the Hospital. When we started doing basic investigations from 10/11/2021 on already recruited patients about 150 patient not attended the clinic due to the Covid 19 situation and various other reasons. In order to collect the missing 150 patients we started the recruitment again from 10/ 11/ 2021. Up to now basic investigations of 302 patients were completed and waiting to recurred another 18 patients.

Any changes to trial outcomes after commencement: Nil

2. Current status

Recruitment status: ~~pending/~~ recruitment continuing to fill the defaulted patients and follow up continuing in the recruited patients/ ~~recruitment complete: follow up continuing/ recruitment complete: follow up complete/ recruitment suspended/ recruitment terminated~~

Number assessed for eligibility: 776

Number recruited and allocated/randomized: 320 Basic Investigation completed in 302patients

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

Arm 1: 160

Arm 2: 160

Losses/exclusions after allocation/randomization (please edit as relevant): Not available because research is not jet completed

Arm 1: -

Arm 2: -

3. Trial output

Date of trial completion ("last patient, last visit"): Not completed

Final sample size: Not available

Summary of Interim/Final data (if available):

Not yet completed.

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).
Not available	

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)
Not available	

Date started - 16/ 10/ 2019

Anticipated end date - 30/06/2021

Date of first enrolment - 16/ 10 / 2019

Basic Investigation Started - 10/11/2021

(delayed due to covid 19 Pandemic)

Recruitment status- Continuing, same time of follow up the recruited patients continuing

Funding source – National Research Council, Sri Lanka

Regulatory approvals – Ethic review committee, Faculty of Medicine, University of Jaffna.

ET R unit, Ministry of Health, Sri Lanka

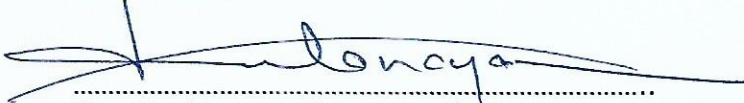
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Clinical Trial flat form of WHO

Secondary study sponsor (If any) – National Research Council, Sri Lanka

Protocol version and date – Version VII

Latest ethical clearance approval – Given on 27. 07.2021 for one year period from
25.07.2021



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(Dr. Karthigesu Kulanayagam)

Name and signature of Responsible Registrant/
Principal Investigator

Date: 28.12.2021