

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: Nil

Any changes to trial outcomes after commencement: Nil

2. Current status

Recruitment status: ~~pending/ recruiting/ recruitment complete: follow up continuing/ recruitment complete: follow up complete/ recruitment suspended/ recruitment terminated~~

Number assessed for eligibility: 543

Number recruited and allocated/randomized: 320

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 jet 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	

Quotation process and all other preparation work of the research were completed by this month. The above-mentioned process was very slow due to the Covid 19 pandemic. Even though I will be able to start the clinical work from July 2021 as all the preparation were completed, I could not be able to start due to the prevailing situation in the Hospital. Around half of the patients are coming for clinic follow up in the diabetic centre and other medical clinic nowadays. Some of the clinics sending drugs to the patients address to avoid the patient arrival to the Hospital. In this above mention situation, I couldn't call the patients to come to the clinic for research purpose. Remain part of the clinical work is a continuous process for total 8 months. If any disturbance in between the process due to the prevailing covid 19 situation the total research process will failed. Their fore I am planning to start the clinical work within the next few months according to the covid 19 situation in the country.

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Name and signature of Responsible Registrant/
Principal Investigator

Dr. K. Kalanayagam.

Date:05.07.2021