

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2016/019

Scientific title of trial: Phase III, Double-Blind, Randomized, Placebo-Controlled Trial to Investigate the Efficacy, Safety and Immunogenicity of a Tetravalent Dengue Vaccine (TDV) Administered Subcutaneously in Healthy Children Aged 4 – 16 Years Old.

Date of commencement (enrolment of first participant): 10 Aug 2016 (first subject was screened to the study from site 3409, Negombo District General Hospital)

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 (Protocol Amendment 3, Version 5.0 dated 28 Jan 2019)

Any changes to trial outcomes after commencement: No

2. Current status

Recruitment status: pending/ recruiting/ **recruitment complete**/ recruitment suspended / recruitment terminated

Number assessed for eligibility: 2721

Number recruited and allocated/randomized: 2100

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

Arm 1: Double blinded either TDV or placebo in a 2:1 ratio

Arm 2: Double blinded either TDV or placebo in a 2:1 ratio

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

Arm 1: Double blinded

Arm 2: Double blinded

3. Trial output

Date of trial completion ("last patient, last visit"): 02 Jun 2021+ 45 days

Final sample size: 20,100

Summary of Interim/Final data (if available):

N/A

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


.....
Dr LakKumar Fernando
Co-ordinating Principal Investigator

Date:

09/02/2019