

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 ☐
4 years ☐ 5 years ☐ 6 years ☐ 7 years ☐
8 years ☐ At completion ☒

1. Baseline data

Any changes to the trial design/ methodology/ protocol after commencement: Yes (Protocol Amendment 6, Version 8.0 Dated 14 September 2021)

Any changes to trial outcomes after commencement: No

2. Current status

Study subject visits completed; Last patient last visit was on 23rd Mar 2024 for Sri Lankan sites.

Number assessed for eligibility: 2721

Number recruited and allocated/randomized: 2100

Number of subjects vaccinated with booster dose: 1326

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): N/A

Arm 1: Double blinded

Arm 2: Double blinded

3. Trial output

Study subject visits completed; Last patient last visit was on 23rd Mar 2024 for Sri Lankan sites.

Final sample size:

Number of subjects enrolled in the main phase: 2100

Number of subjects enrolled in the booster phase: 1326

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)
Efficacy of a tetravalent dengue vaccine in healthy children aged 4–16 years: a randomised, placebo-controlled, phase 3 trial	Efficacy of a tetravalent dengue vaccine in healthy children aged 4–16 years: a randomised, placebo-controlled, phase 3 trial Biswal, ShibadasConcepción, Alys et al. The Lancet, Volume 395, Issue 10234, 1423 – 1433 DOI: https://doi.org/10.1016/S0140-6736(20)30414-1



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