

Progress Report: Sri Lanka Clinical Trials Registry

SLCTR registration number: SLCTR/2022/018

Scientific title of trial: A cluster randomized, placebo control trial to evaluate the efficacy of a spatial repellent (Mosquito Shield™) against Aedes-borne virus infection among children ≥ 4–16 years of age in the Gampaha District, Sri Lanka

Date of commencement (enrolment of first participant): 02 Mar 2023

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

1. Baseline data

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

Protocol Version 9.2:

Sample size calculation was changed to be aligned with changes to Statistical Analysis Plan

- **Power calculations: Updated quantities (coefficient of variation, expected effect size) are still more conservative than the corresponding measured quantity in Peru cRCT.**
- **Design change: Clusters will now be distributed evenly by arm across three MOH regions of Gampaha (strata), which have moderately different risk levels. The stratified randomization necessary to ensure an even distribution of SR and placebo clusters within each stratum will alter the power to detect a difference.**

Any changes to trial outcomes after commencement:

Not applicable

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: **Not applicable**

Number recruited and allocated/randomized:

Number of households recruited: 2441

Number of children recruited for longitudinal cohort: 4153

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

Not applicable.

Arm 1:

Arm 2:

Losses/exclusions after allocation/randomization (please edit as relevant):
Not applicable.

Arm 1:

Arm 2:

3. Trial output

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

Final sample size: **Not applicable**

Summary of Interim/Final data (if available):

Not applicable

Abstract presentations of results at scientific meetings: **Not applicable**
Note: please include a URL link or scanned copy of the abstract

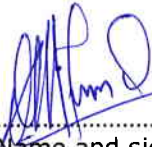
Title of Abstract	Full citation (please include authors, date, title of conference and place of presentation, page number of abstract).

Publications: **Not applicable**

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)

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for
Name and signature of Responsible Registrant/
Principal Investigator

Dr. D.S.A.F. Dheerasinghe

Date: 23/07/2023