

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 \geq 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: 3086 (number of households attended at baseline blood sample collection-2444)

Number of children recruited for longitudinal cohort: 5141 (number of children attended at baseline blood sample collection-4177)

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:

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).
Cluster randomized placebo-controlled community trial on Spatial Repellent in reducing Aedes-borne viruses in the Gampaha district, Sri Lanka: challenges and solutions.	Tissera, H., Dheerasinghe, D. A. F., Kanatiwela-de Silva, C., de Silva, Achee, N. L., Greico, J. (2023). Cluster randomized placebo-controlled community trial on Spatial Repellent in reducing Aedes-borne viruses in the Gampaha district, Sri Lanka: challenges and solutions. Asia-Pacific Conference on Mosquito and Vector Control (AMV), Thailand
Mosquito control products on the retail market in Gampaha District, Sri Lanka.	C Kanatiwela de Silva, A Casella, A Dheersinghe, W Kathriarachchi, R Fernando, N Liyanage, L Baker, D Piccinini, J Grieco, N Achee, S Harvey, HA Tissera (2024). Mosquito control products on the retail market in Gampaha District, Sri Lanka. 7th Asia Dengue Summit, Malaysia
Development and validation of an in-house Dengue IgG ELISA to detect past dengue infections.	ST Ramu, M Dissanayake, C Kanatiwela-de Silva, R Rizan, N Dasanthi, S Danasekara, L Gomes, C Jeewandara, N Achee, J Grieco, HA de Silva, HA Tissera, GN Malavige (2024). Development and validation of an in-house

	Dengue IgG ELISA to detect past dengue infections. 7th Asia Dengue Summit, Malaysia.
Community-Based Trial Assessing Mosquito Shield TM Efficacy Against Aedes-Borne Viruses: Engaging Communities for Better Impact	C Kanatiwela de Silva, N Achee, A Dheersinghe, J Grieco, HA de Silva, HA Tissera (2024). Community-Based Trial Assessing Mosquito Shield TM Efficacy Against Aedes-Borne Viruses: Engaging Communities for Better Impact. 137th Anniversary International Medical Congress, Sri Lanka

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)
A cluster-randomized, placebo-controlled 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: study protocol (the AEGIS program).	Tissera, H., Dheerasinghe, D.S.A.F., Malavige, N. et al. A cluster-randomized, placebo-controlled 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: study protocol (the AEGIS program). <i>Trials</i> 24, 9 (2023). https://doi.org/10.1186/s13063-022-06998-z
The current roadmap to global recommendation of spatial repellents for public health use.	Achee, N., Perkins, T., Moore, S. et al. Spatial repellents: The current roadmap to global recommendation of spatial repellents for public health use. <i>Curr Res Parasitol Vector Borne Dis.</i> (2022) https://doi.org/10.1016/j.crpvbd.2022.100107

.....
 Name and signature of Responsible Registrant/
 Principal Investigator

Dr. D.S.A.F. Dheerasinghe

Date: 03/09/2024