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A trial to assess the effectiveness of a novel mosquito insecticide dissemination device to reduce infection by dengue virus

Submission date
13/12/2018

Recruitment status
No longer recruiting

Registration date
31/01/2019

Overall study status
Completed

Last Edited
04/07/2019

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dengue is a disease caused following infection by dengue virus, which is transmitted through the bite of an infected mosquito. Currently it is estimated that 4 billion individuals in over 100 countries are at risk of being infected. Annually, there are an estimated 400 million infections, about a quarter of which lead to symptoms and can result in serious disease requiring hospitalisation and even in death. Over the last decade the virus has spread globally throughout the tropics and even occurs sporadically in more temperate regions. There is no current effective vaccine and mosquito control remains the major means with which to reduce the chances of being infected with the virus. Current mosquito control approaches, however, are proving insufficient. The aim of this study is to assess the effectiveness of a novel mosquito control tool in reducing the burden of dengue in children in the Philippines. This tool attracts mosquitoes which then pick up insecticide on their feet, fly off and which they then deposit into the small bodies of water where the mosquito lays her eggs naturally. The insecticide interferes with the development and growth of the mosquito larvae, which subsequently die. The insecticide is a mimic of an insect growth hormone and has no toxicity for vertebrates (mammals, birds, lizards, frogs, fish).

Who can participate?
Children age 6-16

What does the study involve?
Participating areas are randomly allocated to the intervention group or the control group. In all areas, 100 children are recruited and a saliva sample taken and stored. In the intervention areas, In2Care traps are placed in the community and maintained for 4 months per year (starting May each year). 2nd and 3rd saliva samples are taken during (end month 2) and after (from month 5) the placement of the traps. This is repeated in year 2. Saliva samples are tested at the end of the intervention period of each year. These rates are compared with control areas where no traps are placed. In a random selection of areas the traps are placed to measure mosquito numbers on a weekly basis before and during the intervention period. This study takes place over 2 years, for two consecutive dengue seasons.

What are the possible benefits and risks of participating?
There are no individual benefits or risks. If proven to work (reducing dengue incidence), this mosquito control method could be employed throughout the community and reduce the overall burden of dengue.

Where is the study run from?
Research Institute for Tropical Medicine (Philippines)

When is the study starting and how long is it expected to run for?
May 2019 to April 2021

Who is funding the study?
Agence Française de Développement (France)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
IP IRB 2018-03

Study information

Scientific Title
Efficacy of the In2Care® auto-dissemination device for reducing dengue transmission: study protocol for a parallel two-armed cluster randomised trial in the Philippines

Acronym

Efficacy of the In2Care® auto-dissemination device

Study objectives
The pupacide pyriproxyfen disseminated through In2Care mosquito traps successfully reduces Aedes aegypti mosquito densities. Implemntation of the traps in a community setting is expected to reduce infection rates with dengue virus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Institute for Tropical Medicine Institutional Review Board, 01/06/2018, ref: 2018-092
2. Institut Pasteur Institutional Review Board, 14/06/2018, ref: 2018-03

Study design
Parallel two-armed cluster randomised trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Dengue virus infection

Interventions
Cluster sites (46) will be selected from within Puroks (smallest administrative unit) that had been classfied according to previous dengue incidence (previous 5 years) and population density. An intervention and a control cluster site will be chosen within each purok. Assignment to intervention or control will be achieved by random number generation (odd number - intervention, even number control).

In all clusters (46), 100 children will be recruited and a saliva sample taken and stored.

In the intervention sites (23), In2Care traps will be placed at an approximate density of 1 /1000m2 and maintained for 4 months per year (starting May each year). 2nd and 3rd saliva samples will be taken during (end month 2) and after (from month 5) the placement of the traps. This will be repeated in year 2. Saliva samples will be analysed in triples at the end of the intervention period of each year. Efficacy will be ascertained through comparing sero-conversion rates in each of 100 children in each of the 46 sites.

In a random selection of 10 intervention sites and 10 cluster sites the trialists will place 20 Gravid Aedes traps to measure adult Aedes aegypti mosquito numbers on a weekly basis prior to and during the intervention period.

A final meeting with the result of the study will be held once all the analyses have been completed (end 2020).

Intervention Type
Device

Phase
Not Applicable

Primary outcome(s)
Sero-conversion to dengue virus, measured using IgG ELISA. The three samples (baseline, during after month 2 of intervention) and after intervention (month 5) from each individual are analysed together at the end of each year's intervention period.

Key secondary outcome(s))
Adult mosquito densities: Gravid Aedes traps weekly count data analysed at end of intervention period of each year

Completion date
30/04/2021

Eligibility

Key inclusion criteria
1. 6-16 years old, male and female individuals
2. Parent/guardian informed consent for the child’s participation in the study
3. For children > 7 years old, required assent for his/her participation in the study

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Children <6 years old
2. Children with known concomitant pathology(ies) at the time of the consent as indicated by parent/guardian
3. Refusal to participate

Date of first enrolment
01/03/2019

Date of final enrolment

31/07/2019

Locations

Countries of recruitment
Philippines

Study participating centre
Research Institute for Tropical Medicine
Filinvest City Alabang, Muntinlupa City
Metro Manila
Philippines
1781

Sponsor information

Organisation
Institut Pasteur

ROR
https://ror.org/0495fxg12

Funder(s)

Funder type
Government

Funder Name
Agence Française de Développement

Results and Publications

Individual participant data (IPD) sharing plan
For each participating child, information on name, age, sex, address, barangay, cluster number, dengue vaccination status, school, class, and subsequent dengue ELISA titres will be recorded using a paper Case Report form that will be subsequently inputted into a designed electronic database (Dryad Data Repository).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes