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Determining the acceptability and efficacy of new approaches for dengue vector control in Cambodia

Submission date
19/10/2015

Recruitment status
No longer recruiting

Registration date
26/10/2015

Overall study status
Completed

Last Edited
10/12/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dengue fever is a common viral infection which is passed on when a person is bitten by an infected mosquito. It is spread by a particular type of mosquito called the Aedes aegypti mosquito, which is common in tropical and sub-tropical areas. When a mosquito bites and infected person and then someone who is not infected, the virus passes into the blood of the uninfected person through the mosquito's saliva. Dengue fever causes symptoms similar to the flu, including headache, high temperature (fever), muscle and joint pain and a distinctive skin rash. At the moment, there are no specific medicines available to treat a dengue infection and there is no vaccine to prevent it. The most important ways to prevent the spread of dengue fever is educate people about the importance of wearing protective clothing and insect repellent, and controlling the mosquito population. One of the best ways to control the mosquito population is to stop mosquito offspring (larvae) from reaching adulthood. Female mosquitos lay their eggs on the inner, wet walls of water filled containers and so by adding guppies (a fish which eats the larvae) or insect growth regulator (a chemical which kills the larvae) to containers kept in houses, the mosquito population can be kept down. In developing countries, the prevention of dengue fever can be greatly limited due to lack of funds and so low cost methods like these could help many people. The aim of this study is to find out whether these low-cost programmes are effective in preventing the spread of dengue fever.

Who can participate?
Every house within villages selected to take part in the study.

What does the study involve?
Participating villages are randomly allocated to one of three groups. Villages in the first group are provided large (more than 50 litres) containers containing guppy fish, and smaller (between 10 and 50 litres) containers containing insect growth regulator (IGR). The villages in these groups are also given behaviour change communication (BCC) messages, to help to explain to people why the guppies and IGR is important, where they can get them, and detail other ways in which they can stop mosquitos from breeding around their houses. Villages in the second group are provided with the large containers containing guppies and the BCC messages. Villages in the

third group are not given any extra help and continue as normal through the course of the study. At the start of the study, and then again at 4, 8 and 12 months, the amount of adult Aedes aegypti mosquitos and Aedes aegypti mosquito larvae in each household is measured.

What are the possible benefits and risks of participating?
Benefits of participating include helping to protect participants from dengue by reducing the number of mosquitos in their houses and providing information about how to keep their families safe. There are no notable risks of participating in this study.

Where is the study run from?
All households within Kampong Cham province (Cambodia)

When is the study starting and how long is it expected to run for?
August 2014 to December 2016

Who is funding the study?
1. Department for International Development (UK)
2. German Society for International Cooperation (Germany)

Who is the main contact?
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Determining the acceptability and efficacy of guppies, pyriproxyfen, and community engagement on dengue vectors in Cambodia: A cluster randomized trial

Study objectives
1. Use of guppies, pyriproxyfen (PPF) and Communication for Behavioural Impact (COMBI) activities will reduce numbers of the dengue mosquito vector Aedes aegypti by reducing its breeding through larval control and source reduction, and increase positive health behaviours on dengue prevention
2. COMBI activities will improve the community's knowledge, attitudes, and behaviour around water use and vector borne disease prevention assessed through the use of baseline/endline surveys and focus group discussions
3. Guppies and Pyriproxyfen are acceptable among the target villages as assessed by an endline survey and focus group discussions

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Cambodian National Ethics Committee for Health Research, 09/10/2014, ref: 0285
2. London School of Hygiene and Tropical Medicine Observational/Interventions Research Ethics Committee, 03/06/2015, ref: 8812

Study design
Three-arm cluster randomised controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Home

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Dengue fever

Interventions

Public Randomization was selected as the method by which to randomize villages to evaluation arms. Village chiefs from all 30 clusters and HC chiefs from all seven HCs were invited to a central point (Prey Chhor Operational District) along with local and national authorities. Locally the concept of “lucky draw” is very popular, so we have decided to randomize the clusters based on this locally accepted method. Each representative from the cluster chose one rolled up paper labelled arm one, two, or three from a bowl. Three large sheets of butcher paper were put up on the wall labelled for each of the evaluation arms. As each representative selected their arm, project staff wrote the village name/s on the paper under that arm. After all clusters were chosen, project staff reviewed the three intervention arms and the role of the village chiefs and health centre staff in the project.

Arm 1: Guppy fish in key containers (>50 L) + direct PPF application (Sumilarv© 2MR) in containers (10-50 L) + COMBI
Arm 2. Guppy fish in key containers (>50 L) + COMBI;
Arm 3. Control (no intervention)

Guppies
The use of guppy fish (Poecilia reticulata) is a low cost, sustainable and effective approach to reduce dengue vector populations, and reduce the risk of dengue transmission. In Cambodia, more than 80% of the Aedes mosquito breeding is detected in key containers such as large water jars, cement tanks and other large containers used for the storage and collection of water for human and animal consumption and washing. Studies also pointed out that these large water jars were the most productive for mosquito pupae compared to other water storage containers and should be targeted for control. These large water storage containers or tanks are suitable for introduction of guppy fish (Poecilia reticulata) to control Aedes mosquitoes. In Cambodia and Lao, it had been demonstrated that the use of guppy fish is a low cost, sustainable and effective approach to reduce dengue vector populations, and reduce dengue transmission. Two guppy fish will be placed per cement jar, drum, or water tank in intervention villages (arms 1 and 2).

Pyriproxyfen Matrix Releaser (Sumilarv© 2MR)
PPF is a juvenile hormone analogue (JHA) that interferes with the metamorphosis of juvenile Aedes mosquitoes, preventing their development into adults and ultimately killing them. PPF has been applied to water containers in Cambodia, using a now discontinued slow-release resin that can be placed into water jars. A new improved slow-release PPF matrix release formulation (Sumilarv© 2MR) has been developed and can help target the containers that are uninhabitable by guppy fish. Sumilarv© 2MR is a novel slow release mosquito larvicide containing the Insect Growth Regulator pyriproxyfen incorporated into a plastic disk. It is designed to be applied to drinking water and is suitable for use in water storage tanks, jars, and other types of containers which can become breeding places for mosquitoes. The slow release of pyriproxyfen prevents mosquito larvae from developing into adults for up to six months even when water is used and replaced frequently. Lab tests have shown no signs of tolerance to PPF after more than 17 generations of exposure to PPF. Although both guppies and PPF have been tested in Cambodia before, they have never been tested in combination, nor has PPF been limited to small containers in which guppies cannot survive. One PPF matrix releaser per 40 L will be placed in jars unsuitable for guppy rearing (those less than 50 L) in all villages in Arm 1.

Communication for Behavioural Impact (COMBI):
The effective implementation of integrated vector management requires mobilization and coordination of the resources needed to achieve and sustain behaviour changes among

populations at risk of dengue. Behaviour change takes place over time, but most social mobilization and communication actions for vector control are sporadic and often include vague or ambiguous messages. The COMBI strategy provides a social mobilization and communication approach that connects knowledge and behaviour, addresses the cost and value of engaging in healthy behaviours, recognizes the gradual stages of behaviour change, and creates a supportive environment for behaviour change. The challenge for vector control is how community participation can be integrated into vector breeding source reduction efforts. Community Health Workers (CHWs) are a vital part of successful COMBI communication and social mobilization activities. The efficacy of our COMBI activities will be assessed through KAP surveys and focus group discussions. COMBI activities will be conducted in all intervention villages (those within arm one and two).

Intervention Type
Mixed

Primary outcome measure
Density of resting adult female Aedes agypti in the household as measured by entomology surveys at baseline, 4, 8 and 12 months.

Secondary outcome measures
1. Proportion of houses surveyed positive for Aedes aegypti larvae and/or pupae in any water container as measured by entomology surveys at baseline, 4, 8 and 12 months
2. Proportion of surveyed containers containing Aedes aegypti larvae and/or pupae as measured by entomology surveys at baseline, 4, 8 and 12 months
3. Number of containers positive for Aedes aegypti larvae and/or pupae per 100 houses surveyed as measured by entomology surveys at baseline, 4, 8 and 12 months
4. Number of pupae per household as measured by entomology surveys at baseline, 4, 8 and 12 months
5. Number of pupae per person as measured by entomology surveys at baseline, 4, 8 and 12 months
6. Percentage of wild caught mosquitos positive for dengue virus as measured by entomology surveys at baseline, 4, 8 and 12 months
7. Proportion of water containers with ≥ 1 guppy fish as measured by entomology surveys at baseline, 4, 8 and 12 months and monthly monitoring by community volunteers
8. Proportion of water containers with at least 1 Sumilarv© 2MR as measured by entomology surveys at baseline, 4, 8 and 12 months and monthly monitoring by community volunteers
9. Percentage of households that have knowledge of mosquitos transmitting dengue and understand that they bite during the day as measured by a knowledge, attitudes, and practice survey at baseline and 12 months

Overall study start date
01/08/2014

Completion date
31/12/2016

Eligibility

Key inclusion criteria
All households

Participant type(s)
All

Age group
All

Sex
Both

Target number of participants
The study includes 30 clusters (10 in each arm) ranging in population from 269-1320 totaling 21,722 participants.

Key exclusion criteria
N/A

Date of first enrolment
27/02/2015

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
Cambodia

Study participating centre
Kampong Cham province
Kampong Cham
Cambodia
-

Sponsor information

Organisation
Malaria Consortium

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Sponsor type
Charity

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Funder(s)

Funder type
Government

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
German Society for International Cooperation (Deutsche Gesellschaft für Internationale Zusammenarbeit)

Results and Publications

Publication and dissemination plan
The principle investigators will ensure that the results of the trial are published regardless of outcome. Every two months results will be shared with the technical steering committee. In addition to reporting the results in peer-reviewed journals, the results will disseminated at the provincial level and national level for all project stakeholders at the end of the intervention period. All documents and study materials will be made available in a tool kit that will be given to all government stakeholders and partners.
The investigators will also disseminate their findings in international scientific conferences. Reporting will follow the guidelines in the CONSORT statement.
Study results will be published in a peer reviewed journal within 18 months after the end of interventions.

Intention to publish date
30/06/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	04/08/2017	10/12/2020	Yes	No
Results article	results	16/02/2018	10/12/2020	Yes	No