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Evaluation of vector control tools for dengue outbreak response

Submission date	Recruitment status	[_] Prospectively registered
14/11/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
05/02/2013	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
05/02/2013	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dengue is on the increase worldwide and better methods to control the mosquitoes that carry the virus to humans are needed urgently. The best methods are:
1. Insecticide methods that aim to kill the adult mosquitoes when they rest on walls and in hidden places inside the home, rather than those that kill the young mosquitoes (the larvae) inside household water containers.
2. Safe and easy methods that are liked by and used regularly by householders living in the high-density communities in modern cities where dengue is most common.

Who can participate?
All householders living in communities within the study area in the city of Bandar Lampung, on the island of Sumatra will be eligible to participate.

What does the study involve?
In a study during one wet season in Indonesia, we will compare old and new methods that kill adult dengue mosquitoes. Four different methods will be tested:
1. Indoor residual spraying (IRS) a team comes to the house and sprays insecticide on all the walls and ceilings inside the house. This is done only one time because its effect should last, so that it continues to kill mosquitoes for many months after treatment.
2. Indoor Space-Spraying (ISS) - using standard insecticidal foggers and practice. Here the fog is delivered inside houses, where the majority of the vector population spends its adult life. This method should leave insecticide residue on the surfaces inside the home, thus providing some sustained effect against adult mosquitos in the days or weeks following treatment.
3. DIY-IRS do-it-yourself IRS here, we will provide each house with cans of aerosol insecticide so that they can spray the walls of their house as often as they wish.
4. Outdoor fogging this is the method commonly used in many parts of the world: the insecticide is sprayed as a cloud of fog outside houses
We will compare these methods by measuring the numbers of mosquitoes inside the houses in each group, in the months following treatment. We will also attempt to compare the number of persons from each group who report to local clinics and hospitals with dengue. We will interview people to try to discover if they liked or disliked anything about the treatments.

What are the possible benefits and risks of participating?
Households receiving effective treatment are likely to benefit from reduced numbers of mosquitoes and a potentially reduced risk of dengue.
The insecticide used has an excellent safety record and has been approved by the World Health Organisation for mosquito control and used worldwide for many years. We do not expect any risks arising from participating in the trial.

Where is the study run from?
The study will run by a team of researchers from the Liverpool School of Tropical Medicine (LSTM) in collaboration with the University of Gadjah Mada (UGM) in Yogyakarta.

When is the study starting and how long is it expected to run for?
The trial will run from November 2012 to June 2013

Who is funding the study?
The study is funded by the European Union - Seventh Framework Programme (FP7).

Who is the main contact?
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Contact information

Type(s)
Scientific

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EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Evaluation of vector control tools for dengue outbreak response: a cluster-randomised controlled trial

Acronym
IDAMS

Study objectives
The study will investigate and compare the efficacy of existing and new insecticide-based tools that target adult female Aedes mosquitoes, to determine which, if any, could reduce domestic populations of Aedes aegypti, the primary mosquito vector of dengue, to levels that could reduce dengue virus transmission in treated communities.

More details on IDAMS can be found at :http://www.idams.eu

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Liverpool School of Tropical Medicine, 01 October 2012, ref: 12/31

Study design
Cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Dengue, severe dengue

Interventions
The trial will compare existing (nos 1 & 2) and novel (3 and 4) approaches for targeting dengue vectors in a high-density urban community:
1. Outdoor fogging (OF) using standard protocols. Space spraying or fogging is the treatment of open spaces with airborne droplets of insecticide to kill flying mosquitoes; delivered by teams of operators using dedicated equipment. Used outdoors, it is timed to coincide with flying times of the vectors (ideally soon after sunrise).

2. Indoor Space-Spraying (ISS) - using standard insecticidal foggers and practice. The principle is the same as treatment 1, but here the fog is delivered inside houses, where the majority of the vector population spends its adult life. This method should leave insecticide residue on the surfaces inside the home, thus providing some sustained effect against adult mosquitoes in the days or weeks following treatment.

3. Indoor Residual Spraying (IRS) standard practice using backpack sprayers; here a liquid spray of insecticide is applied directly to the walls inside the home by teams of operators using dedicated equipment; a frontline highly effective method for malaria control for over 50 years, it has never been evaluated for its potential against Aedes aegypti as a dengue prevention method. A single treatment can remain effective for over 9 months.

4. DIY (do-it-yourself) Indoor Residual Spraying (DIY IRS) here, householders deliver residual treatment of their own homes using commercially available residual insecticide preparations. This is an entirely novel approach that has not been evaluated previously for any vector-borne disease.

5. Untreated controls receive no treatments by the study, but remain subject to any existing local procedures.
All treatments will use the same pyrethroid insecticide, Lambdacyhalothrin (Icon; Syngenta), in one of three formulations:-
5.1. Icon EC (emulsifiable concentrate) for outdoor fogging and indoor space spraying; diluted in kerosene or diesel and delivered @ 1-2 gal/ha (outdoors) or at a fixed period of 30-40 secs discharge/room (indoors)
5.2. Icon CS (capsule suspension) for indoor residual spraying; this microencapsulated formulation has improved lifespan and therefore extends the duration of effect after a single treatment; application rate of 20-30mg a.i./m2
3. Icon CS handheld domestic sprayers for DIY-IRS. This method has never been evaluated for its use against tropical vectors. An over-the-counter formulation of Icon, the insecticide concentration is low (0.05% icon) and protective clothing or breathing protection are not recommended. Lambdacyhalothrin has an excellent safety profile (low WHO hazard category, class 3 unlikely to present acute hazard in normal use) and approved by WHOPES for indoor use.

Five surveys will be conducted: Baseline and 0.5, 2 and 5 months post intervention. The trial will cease at 5 months, which is the expected duration of the wet season and consequently, maximum duration of a typical dengue outbreak in Sumatra.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Efficacy of the intervention will be determined by measuring a range of entomological indices.

Acceptance and other perceptions of the interventions will be evaluated using brief questionnaire surveys at baseline and final follow-up.
1. Measure the impact of each treatment on the adult and larval mosquito population densities in the clusters. Dengue vector populations will be measured using the Adult index (AI - proportion of houses positive for adult Ae. aegypti) and standard Stegomyia indices:

1.1. Breteau index (BI - number of containers with immature vector stages/100 houses), House index (HI - percentage of houses found with immature stages of Ae. aegypti) and container index (CI - percentage of water-holding containers found with immature stages of Ae. aegypti). We will also measure the Pupal index (PI - number of pupae per number of people), a proxy for adult populations, and deploy ovitraps as sensitive indicators of Aedes spp. presence or absence.

Secondary outcome measures
Interview surveys used to determine:
1. Household characteristics
2. Precious and current vector control intervention
3. Understanding of the local population's knowledge, attitudes and practice about dengue prevention and control, and the interventions being tested
4. Insecticide-susceptibility assays undertaken before, at follow-up surveys and after intervention

Each house will be geo referenced with a handheld global positioning system receiver to permit potential effects between clusters to be quantified.

Overall study start date
01/11/2012

Completion date
30/05/2013

Eligibility

Key inclusion criteria
All occupied households

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2,500 households

Key exclusion criteria
1. Business-only premises
2. Unoccupied premises

Date of first enrolment
01/11/2012

Date of final enrolment
30/05/2013

Locations

Countries of recruitment
England

Indonesia

United Kingdom

Study participating centre
Liverpool School of Tropical Medicine
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Sponsor information

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Funder(s)

Funder type
Government

Funder Name
European Union (EU) (Belgium) - Seventh Framework Programme (FP7): Grant agreement no. 21803

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration