

Strategies for the prevention of dengue (Estrategias para la prevencion del Dengue)

Submission date 08/05/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/06/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 18/06/2009	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DGCD-FA2-95900-4

Study information

Scientific Title

A cluster randomised trial evaluating community involvement in Aedes control and dengue prevention

Study objectives

An integrated community-based environmental management strategy is more effective in terms of reductions in entomological indices in comparison to routine Aedes control.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of the Pedro Kouri Institute (Comité de ética y revision del Instituto Pedro Kouri), Havana, Cuba (affiliated to the Ministry of Health [MINSAP]), approved in September 2003 (ref: 0103015)

Study design

Single-centre cluster randomised controlled trial (blinding not possible).

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

Aedes aegypti infestation/ dengue fever

Interventions

Intervention communities: A community-based environmental management approach combined with the routine national dengue vector control programme. Dengue control activities were identified, designed, planned and executed by the community itself, with the support of newly set-up local Community Working Groups.

Control communities: Routine Aedes aegypti control programme (entomological surveillance, source reduction, selective adulticiding and health education)

Total duration of interventions/ follow-up: 13 months

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Aedes infestation levels, assessed every 11 days over the total duration of follow-up (13 months):

1. House Indices (HI): number of houses positive for at least one container with Aedes aegypti immature stages/100 inspected houses
2. Breteau Indices (BI): number of containers positive for Aedes aegypti immature stages/100 inspected houses
3. Pupal Indices (PI): number of Aedes aegypti pupae/inhabitant

In cycles of 11 days, the National Vector Control programme conducted routine entomological surveys in all dwellings of the municipality. This provided the entomological information for all clusters for the period of January 2005-February 2006.

Secondary outcome measures

1. Proportion of breeding sites positive for first and second instar larvae. Data were collected as for the primary outcome measures every 11 days over 13 months.
2. Percentage of blocks (approximately 20-50 houses per block) repeatedly positive for larvae. Data were collected as for the primary outcome measures every 11 days over 13 months.
3. Level of community participation based on the Rifkin criteria, assessed 12 months after the start of interventions

Overall study start date

01/09/2004

Completion date

31/12/2007

Eligibility**Key inclusion criteria**

1. Circumscriptions (i.e. neighbourhoods) of central urban Guantanamo
2. Community approval

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

32 circumscriptions of each approximately 500 houses

Key exclusion criteria

1. Circumscriptions without community approval

Date of first enrolment

01/09/2004

Date of final enrolment

31/12/2007

Locations

Countries of recruitment

Belgium

Cuba

Study participating centre

Institute of Tropical Medicine

Antwerp

Belgium

2000

Sponsor information

Organisation

Directorate-General for Development Co-operation (DGDC) (Belgium)

Sponsor details

FOD Buitenlandse Zaken

Buitenlandse Handel en

Ontwikkelingssamenwerking

Karmelietenstraat 15

Brussels

Belgium

1000

Sponsor type

Government

Website

<http://www.dgic.be/en/index.html>

Funder(s)

Funder type

Government

Funder Name

Directorate-General for Development Co-operation (DGDC) (Belgium) (project ref: 95900)
(framework agreement between the Institute of Tropical Medicine of Belgium and of Cuba)

Funder Name

Ministry of Health (MINSAP) (Cuba)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/06/2009		Yes	No