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

Submission date	Recruitment status	[_] Prospectively registered
08/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/06/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/06/2009	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

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

Study type(s)
Prevention

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(s)
Aedes infestation levels, assessed every 11 days over the total duratin 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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Other

Sex
All

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)

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

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