

Camino Verde: sustainable dengue control

Submission date 15/10/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/10/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/07/2017	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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IDX-2009

Study information

Scientific Title

Camino Verde: a randomised controlled cluster trial to reduce dengue risk in Nicaragua and Mexico through evidence-based community mobilisation

Acronym

Camino Verde

Study objectives

Evidence-based community mobilisation is no less effective in controlling dengue than temephos in drinking water. Informed community mobilisation adds value through other health-related advantages and increased social capital.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The pilot project in Nicaragua received human subjects research approval from the University of California, Berkeley (ref: UCB 2004-6-179); this was renewed each year from 2004 - 2009. The IRB in the Nicaragua Ministry of Health also approved the project in 2004. Approvals are pending for the current phase from UCB, the Universidad Autónoma de Guerrero, Mexico, and CIETCanada.

Study design

Randomised controlled cluster trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Dengue infection

Interventions

Feedback of for dengue immunological status and entomological indicators informs community-led pesticide-free interventions (for example, cleaning and sealing water tanks). Gender stratified focus groups and then community meetings will discuss possible interventions, based on this evidence. A small community action research team (CART) in Mexico and local brigadistas in Nicaragua (three to five people in each community) will receive training in pesticide free vector control and provide the continuity from season to season.

The duration is two dengue seasons - two years.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Measured after the first dengue season (year 2) and in the third year, at the end of this phase of the trial:

1. Childhood recent dengue infection (age 4 - 9 years) as estimated by saliva IgG (two samples with 4-fold increase in titre)
2. Entomological index (pupal density)

Secondary outcome measures

Measured after the first dengue season (year 2) and in the third year, at the end of this phase of the trial:

"CASCADA" of intermediate outcomes:

1. Conscious knowledge regarding dengue, its prevention and control
2. Attitudes (in relation to different options for dengue control; is it worth doing this or that action)
3. Subjective norms (what neighbours do) and positive deviations from a negative norm
4. Intention to change behaviour in the future and to implement preventive action
5. Agency (collective and individual self-efficacy - feel capable of carrying out the actions in a sustained manner and with one's own resources)
6. Socialisation (discussions about dengue, its prevention, control and consequences)
7. Action (interventions, practices)
8. Health literacy, resilience, social capital

Overall study start date

01/11/2009

Completion date

30/10/2012

Eligibility

Key inclusion criteria

All residents of 100 - 120 households in the 170 census enumeration areas, in each country selected as a random sample of the most recent population census.

Participant type(s)

All

Age group

All

Sex

Both

Target number of participants

50,000 individuals in 9,000 households in 170 clusters in two countries

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/11/2009

Date of final enrolment

30/10/2012

Locations

Countries of recruitment

Mexico

Nicaragua

Study participating centre

CIET

Acapulco

Mexico

CP39640

Sponsor information

Organisation

CIET Tropical Disease Research Centre (Mexico)

Sponsor details

c/o Dr Neil Andersson

Universidad Autónoma de Guerrero

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Sponsor type

Research organisation

Website

<http://www.ciet.org>

ROR

Funder(s)

Funder type

Other

Funder Name

A Swiss Private Foundation (Switzerland)

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	08/07/2015		Yes	No
Other publications	ethical issues	30/05/2017		Yes	No
Other publications	secondary analysis	30/05/2017		Yes	No
Results article	results	30/05/2017		Yes	No
Results article	results	30/05/2017		Yes	No