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Diarrhoea and dengue control in rural primary schools in Colombia

Submission date
02/01/2012

Recruitment status
No longer recruiting

Registration date
28/02/2012

Overall study status
Completed

Last Edited
28/12/2022

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
Diarrhea and dengue fever are major diseases which, between them, kill millions of people around the world each year. Water is important for both diseases. Dirty drinking and cooking water is a common cause of diarrhea, and dengue is spread by mosquitoes which can breed in water containers. In this study we want to see whether improving water hygiene and storage can reduce the two diseases in schoolchildren. We are doing the study in schools for three main reasons. First, dengue mosquitoes tend to bite a lot in the mornings when children are likely to be in school. Also, not all schools in the study area have hygienic drinking water, so children may catch diarrhea-causing organisms there. Finally, we want to teach children something about how people catch these diseases which will hopefully encourage preventive measures at home.

Who can participate?
We are doing the study in rural primary schools in the municipalities of La Mesa and Anapoima, Cundinamarca department. The school principal has to agree before the school can take part and we wont we include large schools (if they have more than 100 pupils and more than five grades) or those which are inaccessible or closed, or those which are involved in any other programme to control diarrhea or dengue. We will record diarrhea and dengue illness in all pupils in grades 1-5 in all selected rural schools. It doesnt matter what age the children are, or whether they are boys or girls, or whether or not they have had diarrhea or dengue or any other illness in the past, but we will only record a childs illness if they agree and if one of their parents also agrees. New children that enter these schools in the middle of the study can also join the study in the same way.

What does the study involve?
We will implement interventions that aim to reduce diarrhea and other interventions that aim to reduce dengue. The participating schools will be randomly allocated to receive either the diarrhea interventions, the dengue interventions, both interventions, or neither of the interventions. The reason for not doing anything in some schools is so that we can tell whether any changes in disease are due to the interventions or to other things which affect all schools, such as having a lot of rain one year.

For diarrhea, we will:
1. Provide drinking water filters
2. Promote hand washing with soap
3. Put lids on as many water storage containers as we can
4. Clean the drinking water storage containers once or twice a term
5. Promote cleaning toilets every day
6. Teach children about diarrhea, water and hygiene

For dengue, we will:
1. Fit windows with curtains made out of nets treated with insecticide
2. Put lids on as many water storage containers as we can
3. Put a different insecticide in any water containers that we cant cover properly with a lid
4. Encourage the schools to tidy up rubbish, especially old containers which can get wet inside
5. Teach children about dengue and about mosquitoes and where they breed

We will measure how well the interventions are working by recording the incidence of diarrhea and dengue in children, and by seeing how many dengue mosquitoes there are in each school.

What are the possible benefits and risks of participating?
In some schools in the study, we will try to make the water cleaner, to reduce the number of mosquitoes, and to teach children about diarrhea and dengue. We hope that these actions will reduce the incidence of diarrhea and dengue in children. In some schools we are going to use net curtains treated with insecticide. This kind of netting has been approved by the World Health Organization to be used this way. However, if held next to the skin, it may produce tingling and similar feelings. Some water containers that we cant cover properly will instead be treated with a different insecticide to stop the mosquitoes hatching out properly. Only non-drinking water containers will be given this insecticide. When used this way there are no known risks to people, and it has been approved by the World Health Organization.

Where is the study run from?
We are asking children and teachers in rural primary schools in the municipalities of La Mesa and Anapoima (Cundinamarca department) to participate. The study will be run from Universidad El Bosque in Bogotá.

When is the study starting and how long is it expected to run for?
We expect the study to start in February 2012 and run until November 2013.

Who is funding the study?
The study is mostly funded by the Research Council of Norway. Also, the Lazos de Calandaima Foundation will pay some of the workers who live in the study area.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Study information

Scientific Title
Reducing diarrhoea in school children and control of the dengue vector Aedes aegypti in rural primary schools in Colombia by targeted disease-specific interventions: a factorial cluster randomized controlled trial

Study objectives
This study investigates whether a set of diarrhoea and dengue interventions will significantly reduce diarrhoea cases and dengue risk factors in rural primary schools.

The implemented interventions will significantly reduce the number of diarrhoea cases, the number of school absence episodes, dengue mosquito infestation, and water contamination compared to control schools.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Ethics Committee, Bosque University, [Comité Institucional de Ética en Investigaciones de la Universidad El Bosque], Bogotá, Colombia, 30/08/2011, ref: 146

Study design
2x2 factorial cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Diarrhoea and dengue

Interventions

Schools, stratified by municipality, are randomized to 1 of 4 study arms: diarrhoea, dengue, combined diarrhoea/dengue interventions, and control.

1. Diarrhoea
1.1. Drinking water filters (ceramic filters).
1.2. Promotion of hand washing with soap. Soap will be provided by the project and pupils will be instructed how to wash their hands and asked to do so before eating and after toilet visits.
1.3. Lids on drinking water storage containers. All containers used for storing drinking water will be provided with appropriately fitted lids covering the opening of the container.
1.4. Cleaning of drinking water storage containers 1-2 times per semester.
1.5. Cleaning toilets on a daily basis.
1.6. Educational campaign through project-designed school curricula on diarrhoea, hand-washing practices, hygiene practices, health and water relationships.

2. Dengue
2.1. Windows will be fitted with insecticide (deltamethrin) treated curtains.
2.2. Water containers will be provided with appropriately fitted lids covering the opening of the container.
2.3. Water containers that cannot be fitted with lids will be treated with pyriproxifen, ai insect growth regulator.
2.4. Larval source control through solid waste management. Clean up and collection campaigns will be arranged by teachers and project staff and carried out by pupils on a monthly basis.
2.5. Educational campaign through project-designed school curricula on dengue, vector biology, ecology, and control; role of solid waste; water and health relationships.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Diarrhoea interventions:
Incidence rate of diarrhoea in school children (from school absence registers and parental confirmation)

Dengue interventions:
1. The Breteau index (number of containers positive of Aedes aegypti immatures /100 schools)
2. Number of adult Aedes aegypti per school

Follow-up data collections at 6, 12, 18, and 24 months.

Key secondary outcome(s))
1. Number of pupil absence episodes and days absent due to diarrhoea (from school absence registers and parental confirmation by telephone confirmation)
2. Number of pupil absence episodes and days due to probable dengue causes (from school absence registers, parents telephone confirmation, and health clinic confirmation). Probable cases defined based on Colombian national criteria.
3. Number of pupil absence episodes and days absent due to all-cause illness, measured by school absence registers
4. Values of a selected set of drinking water quality parameters, measured by surveys of drinking

water parameters in schools.
5. Values of calculated knowledge, attitudes and practices (KAP) scores, measured by questionnaires.

Follow-up data collections at 6, 12, 18, and 24 months (data for points 1-3 will be recorded daily and collected weekly).

Completion date
15/11/2013

Eligibility

Key inclusion criteria
1. Schools:
1.1. All rural primary schools, with grades 1-5, within the boundaries of La Mesa and Anapoima municipalities, Tequendama province, Cundinamarca department, Colombia
1.2. Written consent of the school principal to participate
1.3. Schools included will not be already involved in any diarrhoeal or dengue control program
2. Pupils:
2.1. All pupils in grades 1-5 in all selected rural schools (name and class of each pupil will be recorded)
2.2. Both assent from the pupil, and written consent from a parent or guardian is needed for children to participate in the trial
2.3. Newly enrolled children will participate (open cohort)

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
515

Key exclusion criteria
1. Schools:
1.1. Schools that are considered logistically impractical to manage
1.2. Large rural schools (colegios, with > 100 pupils and > five grades)
1.3. Those which are inaccessible or closed
1.4. Schools not wishing to participate
2. Pupils:
2.1. Pupils without either assent or consent
2.2. Temporary visitors to the study areas
2.3. Outgoing pupils (open cohort)

Date of first enrolment
01/02/2012

Date of final enrolment
15/11/2013

Locations

Countries of recruitment
Colombia

Norway

Study participating centre
Norwegian University of Life Sciences
Ås
Norway
1432

Sponsor information

Organisation
Norwegian University of Life Sciences (Norway)

ROR
https://ror.org/04a1mvv97

Funder(s)

Funder type
Research council

Funder Name
Norges Forskningsråd (ref: 201349)

Alternative Name(s)
Forskningsrådet, Norwegian Research Council, Research Council of Norway, The Research Council of Norway

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Norway

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/11/2016		Yes	No
Results article	Results on knowledge, attitudes and practices	27/12/2022	28/12/2022	Yes	No
Protocol article	protocol	03/10/2012		Yes	No