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Distributing and promoting insecticide treated nets through schools in Mali

Submission date	Recruitment status	[_] Prospectively registered
08/11/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/01/2011	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
04/10/2016	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Malaria is an infectious disease which is common in tropical and subtropical countries, caused by a microscopic parasite which is spread from person to person by mosquitos. It can be serious disease if it is not treated quickly and effectively. School-aged children are rarely targeted by malaria control, yet the prevalence (commonness) of malaria infection in this age group often exceeds that seen in younger children and could affect school participation and performance. This study is evaluating the impact of a school based malaria control program which involves distribution and promotion of long lasting insecticidal nets (LLINs), malaria education and treatment. The aim of this study is to find out if the malaria prevention program can reduce levels of malaria infection, anaemia (low levels of haemoglobin – the protein in blood that binds to oxygen) and improve attention and performance in school.

Who can participate?
Children aged 5-15 who attend participating primary schools in the Sikasso Region of Southern Mali.

What does the study involve?
Participating schools are randomly allocated to one of two groups. In the first group, all school children are given two long lasting insecticidal nets (one for themselves and one for their younger siblinds) and are trained to promote their use in their homes. They also receive one dose of malaria treatment at the end of the malaria season and start of the school year (referred to as intermittent parasite clearance –IPC). In the second group, participants continue as normal, but are given a change to receive the nets and treatment at the end of the study. At the start of the study, mid-term (after the LLIN distribution and promotion) and endline (after the IPC) participants in both groups have a finger prick test to take a sample of blood, which is then tested for haemoglobin levels and levels of the malaria parasite in the blood. In addition, attention in the classroom is also measured using concentration tests.

What are the possible benefits and risks of participating?
Participants benefit from receiving long lasting insecticidal nets (LLINs), malaria prevention education lessons and a malaria treatment. The main risk of participating is the risk of pain when having blood samples taken.

Where is the study run from?
80 primary schools in Sikasso region, Southern Mali (Mali)

When is the study starting and how long is it expected to run for?
February 2010 to April 2013

Who is funding the study?
Save the Children (USA)

Who is the main contact?
Ms Natalie Roschnik
n.roschnik@savethechildren.org.uk

Contact information

Type(s)
Scientific

Contact name
Ms Natalie Roschnik

Contact details
71 Chemin des Choseaux
Menthon St Bernard
France
74290
+33 450 44 80 02
n.roschnik@savethechildren.org.uk

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Malaria control programme in schools: a cluster randomised study evaluating the health and educational benefits in Mali

Study objectives
Study hypothesis as of 19/09/2016:
Distributing and promoting Long Lasting Insecticide-treated Nets (LLINs) and intermittent malaria clearance through schools reduces the prevalence of Plasmodium falciparum infection and anaemia and improves school attention and performance amongst school children.

Original hypothesis:
Distributing and promoting Long Lasting Insecticide-treated Nets (LLINs) through schools reduces the prevalence of Plasmodium falciparum infection and anaemia and improves school attention and performance amongst school children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval statement added 19/09/2016:
Ethical Committee of the National Institute of Research in Public Health in Mali, 05/11/2010, ref: 00013/10/CE-INRSP (following an amendment to the study protocol, a second approval was received on 01/12/2011)

Original ethical approval statement:
Ethical Committee of the Institut National de Recherche en Santé Publique (INRSP) approved on the 25th October 2010 (preliminary approval)

Study design
Cluster randomised waitlist controlled trial

Primary study design
Interventional

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Malaria, anaemia

Interventions
Interventions as of 19/09/2016
Two LLINs were provided freely to each child enrolled in the study, one for him/herself and another for another member of the family (preferably a younger sibling). Children were taught about malaria using active participatory methods encouraging children to use of LLINs and promote their use in their homes. All school children also received a single annual treatment of artesunate plus sulfadoxine-pyrimethamine (AS/SP) at the end of the malaria transmission season, to clear them of malaria parasites (intermittent parasite clearance).

Save the Children also used the Community Action Cycle, a proven community mobilisation approach developed by Save the Children and other partners to mobilise the community to increase bed net use generally.

The LLIN distribution and promotion was conducted in the intervention group in April 2011 and the intermittent parasite clearance was conducted in December 2011 in all intervention schools. The control schools received the same interventions the following school year (October-April 2012).

Original interventions:
Two LLINs will be provided freely to each child enrolled in the study, one for him/herself and

another for another member of the family (preferably a younger sibling). A pupil booklet and teachers guide on the effective use of LLINs by schoolchildren and their families, developed and evaluated by Population Services International in Kenya, will be adapted to the Malian context and teachers trained to use it with their class.

Save the Children will also use the Community Action Cycle, a proven community mobilisation approach developed by Save the Children and other partners to mobilise the community to increase bed net use generally.

The duration of the treatment in the intervention group will be the FY11 school year: December 2010 - June 2011 and the duration of treatment in the control group will be the FY12 school year: December 2011 - June 2012.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Artesunate plus sulfadoxine-pyrimethamine (AS/SP)

Primary outcome(s)
Prevalence of anaemia, assessed through finger prick blood sample taken at the point of survey to record haemoglobin concentrations using a portable HemoCue photometer (HemoCue, Angelhom, Sweden). Measured at baseline and one year.

Key secondary outcome(s))
Measured at baseline and one year:
1. Prevalence and incidence of Plasmodium falciparum parasitemia, assessed through finger-prick blood samples for the preparation of a thick and thin blood smear as well as a rapid diagnostic test (RDT)
2. Classroom attention assessed by concentration tests adapted from the TEA-Ch (Tests of Everyday Attention for Children) battery for group administration in groups of 15 or fewer

Removed 19/09/2016:
3. School absenteeism assessed through random spot checks

Completion date
01/04/2013

Eligibility

Key inclusion criteria
The target population in this evaluation includes children (aged 5 - 15 years, either sex) attending primary schools and the accessible population includes the children attending the participating primary schools in classes 1 - 6 in the districts of Sikasso and Yorosso in Sikasso Region. Inclusion criteria are:
1. Pupil enrolled at participating schools
2. Provision of informed consent from parent or guardian
3. Provision of assent by student

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
15 years

Sex
All

Key exclusion criteria
Pupils unwilling to participate in the study

Date of first enrolment
01/11/2010

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
Mali

Study participating centre
Save the Children International
Hamdallaye ACI 2000
Bamako
Mali
B.P. 3105

Sponsor information

Organisation
Save the Children

ROR
https://ror.org/036jr6x18

Funder(s)

Funder type
Charity

Funder Name
Save the Children

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sian Clarke: Sian.Clarke@lshtm.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes