ISRCTN07404145 https://doi.org/10.1186/ISRCTN07404145

Entomological research, training and prevention strategies for malaria in Africa

Submission date	Recruitment status	[_] Prospectively registered
18/04/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/04/2017	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Malaria is a serious tropical disease caused by a type of parasite known as Plasmodium that is spread by mosquitoes. Malaria can be prevented by sleeping under a mosquito net treated with insecticide (long lasting insecticidal mosquito nets [LLINs]), by applying insecticide to the inside of dwellings (indoor residual spraying [IRS]), or by covering the walls with plastic sheeting treated with carbamate insecticide (CTPS). However, efforts to control and eliminate malaria in Africa are being challenged by parasites becoming resistant to antimalarial drugs and mosquitoes becoming resistant to insecticides. The aim of this study is to find out whether combinations of LLINs and IRS or an IRS-like treatment (CTPS) are more effective at protecting against malaria than LLINs alone.

Who can participate?
Children aged 0-71 months living in the 28 selected villages

What does the study involve?
Participants are randomly allocated to use one of four malaria prevention strategies:
1. LLINs for pregnant women and children aged under 6
2. LLINs to cover all sleeping units
3. LLINs for pregnant women and children aged under 6 and full coverage with carbamate-IRS
4. LLINs to cover all sleeping units and full coverage with CTPS
Malaria infection rates are compared between the four groups.

What are the possible benefits and risks of participating?
Using a combination of LLINs and IRS could be more effective at reducing malaria-related illness.

Where is the study run from?
The health district of Ouidah-Kpomassè-Tori Bossito (OKT) (Benin)

When is the study starting and how long is it expected to run for?
July 2008 to December 2009

Who is funding the study?
1. Ministry of Foreign and European Affairs (France)
2. Institute of Development Research [Institut de Recherche pour le Développement] (France)
3. The President's Malaria Initiative (PMI) (USA)

Who is the main contact?
Dr Vincent Corbel

Contact information

Type(s)
Scientific

Contact name
Dr Vincent Corbel

Contact details
Institut de Recherche pour le Développement/Centre de Recherche Entomologique de Cotonou (IRD/CREC)
Quartier les cocotiers
Près de la direction générale des impôts
01 BP 4414 RP
Cotonou
Benin
00229

Additional identifiers

Protocol serial number
FSP project 2006-22

Study information

Scientific Title
Combining vector control interventions for malaria control in pyrethroid resistance area: a cluster randomized controlled trial in Benin, West Africa

Study objectives
The combination of long lasting insecticidal mosquito nets (LLIN) and indoor residual spraying (IRS) or an IRS-like treatment (i.e. carbamate treated plastic sheeting, CTPS) confer protection against malaria and better management of pyrethroid-resistance in vectors than LLIN alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Ethical Committee for Medical Research (CNPERS), Benin, 16/12/2010

Study design

Cluster randomized controlled trial with 18 months follow-up

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Malaria prevention by vector control strategies

Interventions
Four malaria vector control interventions were evaluated as follows:
1. LLIN-targeted coverage [TLLIN] to pregnant women and children <6 years that served as a control group
2. LLIN-universal coverage of all sleeping units [ULLIN]
3. LLIN-targeted coverage to pregnant women and children <6 plus full coverage of Carbamate-IRS [TLLIN+IRS]
4. LLIN-universal coverage of sleeping units plus full coverage of CTPS lined up to the walls of the household [ULLIN+CTPS]

Intervention Type
Other

Primary outcome(s)
Incidence density rates of Plasmodium falciparum clinical malaria in children aged under 6 years

Key secondary outcome(s))
1. The prevalence and parasite density of asymptomatic infections among children aged under 6 years
2. The entomological inoculation rates [(EIR), as defined by the number of infected bites per human per year]
3. The human biting rates [(HBR), as defined by the number of bites per human per year]
4. The prevalence of pyrethroid resistant 1014F kdr allele in malaria vectors

Completion date
23/12/2009

Eligibility

Key inclusion criteria
1. Children aged 0-71 months
2. Lives in villages selected for study

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
0 months

Upper age limit
71 months

Sex
All

Key exclusion criteria
1. Inhabitants older than 6 years
2. Children not living in selected villages

Date of first enrolment
09/07/2008

Date of final enrolment
23/12/2009

Locations

Countries of recruitment
Benin

Study participating centre
Institut de Recherche pour le Développement/Centre de Recherche Entomologique de Cotonou (IRD/CREC)
Cotonou
Benin
00229

Sponsor information

Organisation
Institute of Development Research [Institut de Recherche pour le Développement] (France)

ROR
https://ror.org/032qezt74

Funder(s)

Funder type
Government

Funder Name
Ministry of Foreign and European Affairs (France) ref: FSP project 2006-22

Funder Name
Institute of Development Research [Institut de Recherche pour le Développement] (France)

Funder Name
President's Malaria Initiative (USA)

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	01/08/2012		Yes	No