ISRCTN30634670 https://doi.org/10.1186/ISRCTN30634670

To assess whether addition of pyriproxyfen to long-lasting insecticidal mosquito nets increases their durability compared to standard long-lasting insecticidal mosquito nets

Submission date
08/07/2014

Recruitment status
No longer recruiting

Registration date
13/08/2014

Overall study status
Completed

Last Edited
17/08/2018

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
Malaria is a major cause of sickness and death in sub-Saharan Africa. Sleeping under an effective and long-lasting insecticidal net will protect people from malaria. Pyrethroid-treated bed nets are one of the major mosquito control methods used against malaria in sub-Saharan Africa. However, there are few places where vector mosquitoes (those that can cause malaria) are fully vulnerable to pyrethroid insecticides, so alternative treatments for nets are required urgently. Here we assess the durability of nets with a new combination of insecticides called permethrin and pyriproxyfen in comparison with a typical permethrin-treated net.

Who can participate?
Village residents who usually sleep on a bed can take part in this study.

What does the study involve?
Participating households in each village will be randomly allocated to receive either permethrin and pyriproxyfen treated nets or permethrin-treated nets. We will distribute the nets at the start of the transmission season and follow net use at the start and end of the transmission season, i.e. from 0 to 36 months after distribution. The effectiveness of the insecticide, chemical content along with net durability and fabric integrity will be recorded immediately after distribution, and then at 6, 12, 18, 24, 30 and 36 months. Routine measurements of indoor temperature and relative humidity will be made in both villages during the study. Residents will be followed for possible side effects of the permethrin and pyriproxyfen treated nets by looking for known asthmatic people during the first month after distribution and pregnancy outcomes will be monitored from antenatal clinic records.

What are the possible benefits and risks of participating?
The results from this study will be of interest to those working on malaria control in Burkina

Faso and other African countries. Although permethrin and pyriproxyfen are safe to humans, they have not been used together on a mosquito net before. For this reason we will monitor any side effects from both the combination nets and the nets just with permethrin.

Where is the study run from?
This study is run from two villages in Burkina Faso.

When is the study starting and how long is it expected to run for?
The study started in March 2014 and runs until May 2017.

Who is funding the study?
Innovative Vector Control Consortium (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
v1.0

Study information

Scientific Title

To assess whether addition of pyriproxyfen to long-lasting insecticidal mosquito nets increases their durability compared to standard long-lasting insecticidal mosquito nets: protocol for a cluster randomized study

Study objectives
Pyriproxyfen combined with permethrin on bednets will be just as durable as standard permethrin-treated nets.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethics Committee for Health Research (Comité d'Ethique pour la Recherche en Santé), 02/05/2014, ref: 2014-0-025
2. National Centre for Research and Training on Malaria (Centre National de Recherche et de Formation sur le Paludisme), 27/03/2014, ref. 2014/025/MS/SG/CNRFP/CIB

Study design
Cluster randomized controlled trial of net durability, with clustering at the level of the compound with entomological outcome measurements.

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
Durability of mosquito nets

Interventions
Two villages will take part in the trial. The compounds within each village will be randomly allocated to receive one of two types of bednets on a 50/50 basis
Control bednet: Olyset net with 2% w/w permethrin incorporated into polyethylene fibres
Intervention bednet: DUO net which contains 2% w/w permethrin and 1% w/w pyriproxyfen incorporated into polyethylene fibres.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Bio-efficacy is either measured as:
1. Percentage adult female mortality 24 hours after exposure to netting
2. Percentage of viable offspring (1st or 2nd stage larvae) relative to the control group
This will be recorded immediately after net distribution and at 6, 12, 18, 24, 30 and 36 months.

Secondary outcome measures
Proportion of nets in 'poor' condition, defined as:
1. Those that are not long enough to be tucked under the mattress
2. Torn or badly damaged
3. Has more than five holes (finger-width, approximate diameter 2 cm)
All outcomes will be measured at 0 weeks, 6, 12, 18, 24, 30 and 36 months.

Overall study start date
01/03/2014

Completion date
30/05/2017

Eligibility

Key inclusion criteria
1. Village residents who sleep in a bed
2. Those that provide their informed consent to participate in the trial

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Approximately 1500 subjects

Key exclusion criteria
1. Non-residents
2. Residents who do not sleep in a bed
3. Those that do not provide their informed consent

Date of first enrolment
01/03/2014

Date of final enrolment
30/05/2017

Locations

Countries of recruitment
Burkina Faso

England

United Kingdom

Study participating centre
Durham University
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Sponsor information

Organisation
Durham University (UK)

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Sponsor type
University/education

ROR
https://ror.org/01v29qb04

Funder(s)

Funder type
Charity

Funder Name
Innovative Vector Control Consortium (UK)

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?
Protocol article	protocol	28/04/2015		Yes	No
Results article	results:	18/08/2018		Yes	No