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To assess whether a combination of two insecticides on mosquito nets provides better protection against clinical malaria than pyrethroid-treated nets

Submission date
13/03/2013

Recruitment status
No longer recruiting

Registration date
03/04/2013

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Malaria is a serious tropical disease spread by mosquitoes. Recent reductions in malaria in sub-Saharan Africa have been associated with the increased use of pyrethroid-treated long-lasting insecticidal nets (LLINs). Pyrethroids are currently the only class of insecticide used for treating nets, and the rapid increase in resistance to pyrethroids in mosquitoes may jeopardise future mosquito control. Nets containing a new combination of permethrin and pyriproxyfen (PPF-LLIN) may enhance malaria control and reduce the spread of pyrethroid-resistant mosquitoes. This study will determine whether PPF-LLINs provide better protection against malaria than LLINs in an area with pyrethroid-resistant mosquitoes.

Who can participate?
Children resident in Burkina Faso, aged 6 months to 5 years old.

What does the study involve?
Participants will be provided with LLINs at the start of the study, and their previous nets will be removed. The LLINs will be gradually exchanged for PPF-LLINs so that at three months before the end of the two-year study all participants will have a PPF-LLIN.

What are the possible benefits and risks of participating?
Study children will benefit from a health check at the surveys and all participants will benefit from the health facility clinical services which will be supported by training and the presence of study nurses in addition to government staff. There are no apparent risks to the safety of individuals or communities in the use of the conventional nets. Permethrin-treated long-lasting nets have been fully evaluated by the WHO Pesticide Evaluation Scheme (WHOPES) and approved for mosquito control. However, PPF-LLINs have not previously been evaluated in the field before, apart from small-scale studies. Whilst we do not anticipate any serious impacts of the combination of permethrin and PPF, since the safety profile of both these active compounds is deemed acceptable by WHOPES, we cannot exclude the possibility that there might be side

effects when using the combination. For this reason it is important to assess adverse events and especially any serious adverse events in study subjects during the course of the study to determine whether there is an excess of side effects associated with the PPF-LLINs.

Where is the study run from?
Durham University (UK)

When is the study starting and how long is it expected to run for?
May 2014 to May 2015

Who is funding the study?
EC Seventh Framework Programme

Who is the main contact?
Prof Steve Lindsay
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
2013-02-011

Study information

Scientific Title
To assess whether addition of a second insecticide to long-lasting insecticidal mosquito nets provides additional protection against clinical malaria over current best practice. Protocol for a two-armed cluster randomized wedge-shaped trial in Burkina Faso

Study objectives

Our hypothesis is that mosquito nets treated with two insecticides will provide significant incremental protection against malaria than pyrethroid-treated nets in an area with moderate levels of pyrethroid resistance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Comite d'ethique pour la recherché en sante, Ministere de la recherché scientifique et de l' innovation, Burkina Faso, 13/05/2014, ref: 2014-3-24
2. School of Biological and Biomedical Ethics Committee, Durham University, UK, 17/01/2014

Study design
Two-armed cluster randomized wedge-shaped trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
Long-lasting insecticidal mosquito nets (LLINs) and new net.

Long-lasting insecticidal mosquito nets (LLINs)
The LLINs distributed will be manufactured by Sumitomo Chemical Company. These LLINs are WHO recommended and meets WHO specifications (http://www.who.int/whopes /Long_lasting_insecticidal_nets_Aug09.pdf) with 2% w/w permethrin incorporated into polyethylene fibres giving adequate release of permethrin for about five years. These nets will be distributed in May 2013, at the beginning of the main transmission season, at no cost to the recipients. We will use white 'extra family' size rectangular nets (180cm wide x 190cm l x 150 cm h) throughout. Government Roll Back Malaria information, education and communication procedures will be followed to encourage correct net use and maintenance. This will include supplying the nets in individual pre-opened bags labelled by the manufacturers.

A new net with two insecticides will be provided by Sumitomo Chemicals and are currently undergoing evaluation by the WHO Pesticide Evaluation Scheme (WHOPES). The nets contain 2% w/w permethrin and another insecticide incorporated into polyethylene fibres giving adequate release of both insecticides for an estimated three years. We will provide white 'extra family' size rectangular nets (180cm wide x 190cm l x 150 cm h) throughout. The new nets will be supplied in individual bags labelled by the manufacturers and they will be distributed to recipients in pre-opened individual sachets in August 2013 in five village clusters and rolled out in a wedge-shaped design at monthly intervals thereafter during the main transmission seasons in 2013 and 2014.

New net distribution will be carried out by the study team in a similar manner to the LLINs.

Intervention Type
Device

Primary outcome(s)
To assess whether a pyrethroid insecticide combined with another class of insecticide incorporated into a LLIN provides added protection against clinical malaria in children compared with pyrethroid-only LLINs (LLIN) over two malaria transmission seasons of follow up.

Key secondary outcome(s))
Efficacy
1. To assess whether two insecticides on LLINs provide added protection compared to LLINs against anaemia and/or parasite prevalence in children.
2. To assess and compare the prevalence of microscopy confirmed gametocyte carriers (GC) in LLINs group versus doublke insecticide-LLIN group.

Safety
To assess whether the double-insecticide LLINs have a safety profile comparable with LLINs in the trial population

Completion date
31/12/2014

Eligibility

Key inclusion criteria
Resident children, aged 6 months to 5 years old will be enumerated and an average of 50 per cluster (range 30-100, depending on village size) will be selected randomly, stratified by age and invited to participate in the clinical surveys and passive case detection (PCD). No distinctions will be made regarding gender, ethnic group, medical condition or physical health.

As is customary in Burkina Faso, sensitisation will start by discussions with community elders and then representatives of the whole study community in order to explain the nature of the study and what will be required during the interventions and investigations. Informed consent will be sought at the village level after sensitization meetings attended by village community leaders and health staff. The key attendees names and roles will be documented for each village. Witnessed written consent will be sought from each net recipient, before net donation and exchange. We will seek written consent from room owners before positioning of mosquito traps, and written informed consent from the parents or caregivers of all enrolled study children. During these procedures it will be made clear that people will be able to leave the study at any time but their original net will not be returned.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
5 years

Sex
All

Key exclusion criteria
Those who have not provided their consent for inclusion in the study

Date of first enrolment
01/05/2014

Date of final enrolment
01/05/2015

Locations

Countries of recruitment
United Kingdom

England

Burkina Faso

Study participating centre
Durham University
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Sponsor information

Organisation
Durham University (UK)

ROR
https://ror.org/01v29qb04

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/08/2018	21/01/2019	Yes	No
Protocol article	protocol	25/03/2015		Yes	No