ISRCTN14487329 https://doi.org/10.1186/ISRCTN14487329

Trial of PermaNet 3-barrier bednets as part of an operational distribution programme in Haut-Katanga province, Democratic Republic of Congo

Submission date
09/08/2024

Recruitment status
No longer recruiting

Registration date
14/08/2024

Overall study status
Completed

Last Edited
13/08/2024

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
The study aims to compare two types of insecticidal bednets used to prevent malaria, PermaNet 3 with PermaNet 3-barrier bednets (BBnets). The study is associated with a programmatic distribution of the bednets in Haut Katanga province, southern Democratic Republic of Congo, which has taken place according to our specified distribution plan in May-June 2023. BBnets are identical to PermaNet 3 except for the addition of a longitudinal upright barrier, which contains the same ingredients (deltamethrin and piperonyl butoxide, PBO) as the roof of a PermaNet 3, and significantly enhances insecticide-resistant mosquito killing capacity.

Who can participate?
Healthy pregnant women aged 15 to 50 years old visiting their first antenatal clinic

What does the study involve?
The study will take place within the health zones of the Lubumbashi area of Haut Katanga. Health areas within the health zones are randomly allocated to receive the 300,000 P3-BBnets available, with all others receiving PermaNet 3. The primary outcome variable for the study is the prevalence of malaria recorded by routine testing of visitors at their first ante-natal clinics (ANC1), which provides an efficient and economical method for data collection. Visitors will be recruited by health centre staff to give their permission to take a rapid diagnostic test (RDT) for malaria and will be treated with artemisinin combination therapy (ACT) if positive; they will also be asked to complete a short questionnaire. All 21 health areas receiving P3-BBnets will be monitored for ANC1 malaria prevalence, as well as 42 areas receiving PermaNet 3. Data will be recorded over a continuous survey period of 3 months within the first year after distribution, during which surveys to characterise the malaria mosquito vector community and their insecticide resistance will also be performed, along with assessments of the hanging of bednets and questionnaires to assess user perceptions of the nets they have received.

What are the possible benefits and risks of participating?
There are no direct benefits but participants will be helping to evaluate malaria control tools which may help their communities in future. There are no expected risks to taking part.

Where is the study run from?
Liverpool School of Tropical Medicine (UK)

When is the study starting and how long is it expected to run for?
October 2023 to June 2024

Who is funding the study?
1. European Regional Development Fund
2. UK Research and Innovation Strength in Places Fund
3. The Bloomsbury Set
4. Against Malaria Foundation

Who is the main contact?
Dr David Weetman, david.weetman@lstmed.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
v2.2

Study information

Scientific Title
Trial of PermaNet 3-barrier bednets as part of an operational distribution programme in Haut-Katanga province, DRC (BBnets)

Acronym
BBnets

Study objectives
PermaNet 3 Barrier bednets reduce malaria prevalence more than PermaNet 3 bednets lacking the barrier

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 01/11/2023, Liverpool School of Tropical Medicine Research ethics Committee (Liverpool School of Tropical Medicine, Liverpool, L35QA, United Kingdom; +44 151 705 3100; LSTMREC@lstmed.ac.uk), ref: 23-035

2. approved 23/10/2023, University of Kinshasa School of Public Health Ethics Committee (University of Kinshasa School of Public Health, Kinshasa, BP 11850, Congo, Democratic Republic; +243 817493194; espec_unikin@yahoo.fr), ref: ESP/CE/163/2023

Study design
Interventional cluster-randomized controlled trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of malaria in antenatal clinic visitors

Interventions
This two-armed study intervention involves the distribution of two types of insecticide-treated bednets to compare PermaNet 3 with PermaNet 3-barrier bednets (P3-BBnets). The study arms are represented by clusters, each of which is an administrative health area. Health areas will be randomised using a random number generator to receive one or the other net type. The nets are distributed as part of a programme and all areas within the study (and in the province generally, beyond the study area boundaries) keep their nets for a period of approximately 3 years until the next programmatic distribution. Participants are women from areas with each type of bednet who are enrolled on the study as they attend their first antenatal clinic appointment. If they agree to be enrolled, they receive a test for malaria and complete a short questionnaire. This provides the data for the study and there is no further observation or follow-up.

Intervention Type
Device

Phase
Phase III

Drug/device/biological/vaccine name(s)
PermaNet 3.0 barrier bednet, PermaNet 3.0 bednet

Primary outcome(s)
Malaria prevalence in antenatal clinic visitors measured using a rapid diagnostic test (RDT) for malaria at one timepoint when visitors attend their first antenatal clinic

Key secondary outcome(s))
User perception and acceptance of barrier bednets measured using a bespoke questionnaire made for the study at the time when the participants are tested for malaria

Completion date
30/06/2024

Eligibility

Key inclusion criteria
Pregnant women visiting their first antenatal clinic

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
15 years

Upper age limit
50 years

Sex
Female

Total final enrolment
6779

Key exclusion criteria
1. Young adolescents (<15 years)
2. Women presenting with symptoms of severe malaria
3. Women suffering from other illnesses requiring prompt treatment
4. Limited capacity to consent assessed by understanding of procedures and requirements of the study

Date of first enrolment
01/12/2023

Date of final enrolment
29/04/2024

Locations

Countries of recruitment
Congo, Democratic Republic

Study participating centre
School of Public Health
University of Kinshasa
Kinshasa
Congo, Democratic Republic
BP11850

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
European Regional Development Fund

Alternative Name(s)
Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, ΕΦΠΡ, EFRR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
UK Research and Innovation Strength in Places Fund

Alternative Name(s)
Fondo Europeo de Desarrollo Regional, Europäischer Fonds für regionale Entwicklung, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Fundo Europeu de Desenvolvimento Regional, ERDF, FEDER, EFRE, ЕФРР, EFRR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
The Bloomsbury Set

Funder Name
Against Malaria Foundation

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2.2	29/09/2024	13/08/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 2.2	29/09/2024	13/08/2024	No	No