

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 14/08/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/08/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

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, EФPP, 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, ΕΦΡΡ, 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
Protocol file	version 2.2	29/09/2024	13/08/2024	No	No