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Comparative evaluation of standard and dual-treated insecticide bednets in Sud Ubangi, Democratic Republic of Congo

Submission date
24/10/2019

Recruitment status
No longer recruiting

Registration date
29/10/2019

Overall study status
Completed

Last Edited
29/11/2022

Condition category
Infections and Infestations

[X] 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
Malaria is the world's most important vector-borne disease, infecting millions and causing over 400,000 deaths, mainly in sub-Saharan Africa. The Plasmodium parasites that cause malaria are transmitted by Anopheles mosquitoes, which in African countries most often bite indoors at night. Sleeping under a bed net, especially if treated with insecticide is a proven way to reduce malaria, and much of the decrease in malaria over the past 10-15 years has been attributed to massive increases in treated net distribution campaigns. After a decade of decline, malaria rates have begun to increase; one major reason for which is widespread mosquito resistance to the pyrethroid insecticides used to treat bednets. For safety reasons only pyrethroids are currently approved as the main insecticide for net treatment, but other compounds can be added which may improve their effectiveness. For example, bednets are available co-treated with both pyrethroid and a molecule called PBO which blocks mosquito enzymes that can cause pyrethroid resistance. These PBO co-treated nets have been demonstrated in a single large-scale clinical trial in Tanzania to be more effective than pyrethroid only nets, but more evidence is required from a range of different countries to justify the greater cost of their distribution when health budgets are often very limited. Such evidence is extremely expensive to accumulate from multiple formal clinical trials but an alternative approach is to monitor the relative effectiveness of PBO and standard nets when both are distributed in the same area as part of an ongoing programme. The aim of this study is to determine which type of net works better, and for how long any benefits last, in the province of Sud Ubangi in the northern Democratic Republic of Congo, which is receiving both types of bednet. The study also aims to increase cost efficiency by monitoring malaria rates in women (living in areas receiving the different net types) as they attend routine ante-natal clinic appointments.

Who can participate?
Women visiting antenatal clinics and households in villages around some of the antenatal clinics included in the study

What does the study involve?
All 16 of the health zones in Sud Ubangi province are involved in the study, with 8 receiving only

standard bednets, 7 receiving only PBO co-treated bednets and 1 receiving both; determined at random. The number of pregnant women tested at antenatal clinics and found to carry malaria infections will be compared between the zones with each net type. Measures of mosquito abundance and resistance will also be compared, along with the durability/quality of nets over time from first distribution.

What are the possible benefits and risks of participating?
There are no significant benefits or risks involved in participating.

Where is the study run from?
The study will be run from the University of Kinshasa School of Public Health in collaboration with health services in Sud Ubangi province, based in Gemena (province capital).

When is study starting and how long is it expected to run for?
November 2019 to May 2023

Who is funding the study?
Against Malaria Foundation (UK)

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

Contact information

Type(s)
Scientific

Contact name
Dr David Weetman

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Additional identifiers

Protocol serial number
SU-ITN_1

Study information

Scientific Title
Comparative evaluation of standard insecticide-treated bednets and co-treated bednets on malaria prevalence in Sud Ubangi, Democratic Republic of Congo: a cluster-randomised trial

Acronym
Sud Ubangi ITN study

Study objectives
The primary study hypothesis is that parasite prevalence will be lower in intervention clusters (health zones receiving PBO co-treated bednets), than in control clusters (health zones receiving standard insecticide only bednets) in Sud Ubangi, Democratic Republic of Congo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 24/09/2019, Liverpool School of Tropical Medicine: Research Ethics Committee (Pembroke Place, Liverpool, L3 5QA, UK; Tel: +44(0)151 705 3100), ref: 19-072
2. Approved 23/09/2019, University of Kinshasa Research Ethics Committee (Ecole de Sante Publique
Comite d'Ethique, Ministere de 1'Enseignement Superieur et Universitaire, Unlversite de Kinshasa Faculte de Medecine: B.P 11850 Kin I, Republique Democratique du Congo)

Primary study design
Interventional

Study design
Cluster randomised trial

Study type(s)
Prevention

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

Interventions
Current interventions as of 29/11/2022:

A total of 16 clusters (provincial health zones) are involved in the study; clusters were randomised to receive a different type of treated bednet by a member of LSTM staff, who will not be directly involved in the study. All houses within the eight zones allocated to group 1 will receive standard (pyrethroid only) bednet; within the seven zones allocated to group 2 will receive a PBO co-treated bednet. Within the remaining zone, the distribution will be mixed with one part receiving each bednet, as dictated by different numbers of bednets available within the distribution programme.

Bednets, supplied by Against Malaria Foundation, will be distributed in Sud Ubangi by IMA World Health in partnership with SANRU (DRC rural health programme). All households in Sud Ubangi will receive sufficient nets to permit coverage of one net per two occupants. At the time of distribution, nets will be hung over sleeping spaces by the distribution team partners with an accompanying education programme to increase correct usage, care and maintenance of nets by

householders. The study team have no role in the distribution or hanging of bednets or the bednet-related education programme.

The study involves:
1. Determination of parasite prevalence in women visiting monthly antenatal clinics
2. Entomological collections for surveillance of insecticide resistance and mosquito abundance and parasite infection
3. Assessment of bednet durability (physical and chemical analysis) and bioefficacy (against mosquitoes) over time

The intervention is not under control of the trial but it is planned by the Ministry of Health to replace the nets after a minimum of 36 months, which could be viewed as the end of the intervention. The follow up is planned to be for 30 months post-distribution.

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Previous interventions:

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Intervention Type
Other

Primary outcome(s)
Current primary outcome measure as of 29/11/2022:

Parasite prevalence (defined as the proportion of positive malaria rapid diagnostic tests) in pregnant women assessed at 0, 6 months, 12 months, 18 months, 24 months, and 30 months after bednet distribution

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Previous primary outcome measure:

Parasite prevalence (defined as the proportion of positive malaria rapid diagnostic tests) in pregnant women assessed at 0, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months after bednet distribution

Key secondary outcome(s)
1. Frequency of molecular markers associated with insecticide resistance in the primary malaria vector mosquito (Anopheles gambiae) is measured from DNA extracted from mosquitoes collected in one half of the study clusters at 0, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months after bednet distribution
2. Mosquito abundance and parasite infection rate (with the infectious sporozoite stage) will be measured in one half of the study clusters at 0, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months after bednet distribution
3. Prevalence and intensity of phenotypic insecticide resistance, assessed using World Health Organization (WHO) tests of insecticide, in 4 study clusters at 0, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months after bednet distribution
4. Bednet durability and bio-efficacy assessed will be measured using WHO guidelines for physical assessment of the area of holes, chemical analysis of insecticide (and PBO) concentrations and capacity of the net material to kill locally-caught mosquitoes in controlled experiments in nets collected from 4 study clusters at 0, 6 months, 12 months, 18 months, 24 months, 30 months, 36 months after bednet distribution

Completion date
01/05/2023

Eligibility

Key inclusion criteria
Women attending first ANC appointment at a clinic that is taking part in the study and who consent to be enrolled in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria

1. Young adolescents (<15 years)
2. Women presenting with symptoms of severe malaria
3. Women suffering from other illness requiring prompt treatment

Date of first enrolment
01/06/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Congo, Democratic Republic

Study participating centre
University of Kinshasa
School of Public Health
Kinshasa
Congo, Democratic Republic
H8Q3+2H Kinshasa

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Charity

Funder Name
Against Malaria Foundation

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon request from Dr David Weetman (david.weetman@lstmed.ac.uk). The participant-level data is basic and involves only a short questionnaire with the addition of the malaria test result. The unanonymised data represent a patient medical record so will be maintained at the Sud Ubangi records office in Gemena Hospital. These data sheets are not intended to be publicly available, but access could be possible with an appropriate (separate) ethical/data protection application, which could be sent to Dr Weetman in the first instance for communication to the local health authority. In anonymised format the data could be made available by the trial team (via Dr Weetman), who will retain (anonymised) records for 5 years from the end of the trial. The trial team will also maintain consent forms for the same 5 year period.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1.2		08/11/2019	No	Yes
Protocol file	version v4.1	26/10/2019	08/11/2019	No	No