Insecticide Treated bedNets (ITNs) for malaria control in Urban Accra

Submission date	Recruitment status No longer recruiting	Prospectively registered	
31/01/2008		☐ Protocol	
Registration date 04/04/2008	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	Individual participant data	
04/06/2019	Infections and Infestations		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

Insecticide Treated bedNets (ITNs) for malaria control in Urban Accra

Study objectives

The main objectives of the study:

- 1. Assess if bednets can be used as rapid, high coverage control method for malaria in urban areas
- 2. Investigate the effect of ITN introduction on malaria, anaemia and anthropometric measurements
- 3. Assess the use of haemoglobin level as a measurement of intervention efficacy by controlling for nutritional and geohelminth confounding factors

Ethics approval required

Old ethics approval format

Ethics approval(s)

- 1. Liverpool School of Tropical Medicine, UK, approved on 23 September 2002 (ref: 02:50). Some amendments to the existing clearance were reviewed on the 30 April 2004 with additional approval granted on 3rd June 2004.
- 2. Noguchi Memorial Institute for Medical Research, University of Ghana, Legon, ethical clearance granted in September 2002

Study design

Non-randomised controlled trial

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Malaria and anaemia

Interventions

Insecticide treated bednets vs no intervention (Control group received bednets after six months)

It was not possible to randomly allocate children to the two arms of the study as the intervention was community based. The insecticide treated nets were distributed in the intervention community and therefore all children surveyed in that community entered the intervention arm. All households with children under 10 and/or pregnant women in the control community received an insecticide treated nets after six months.

Duration of intervention: 6 months (although the insecticide treated nets remained the property of the study subjects)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The following were assessed at enrolment, 3 and 6 months:

- 1. Moderate anaemia, provisionally defined as a haemoglobin level <9 g/dl
- 2. Haemoglobin level as a continuous variable (in g/dl)
- 3. Density of infection defined as parasitaemia >5,000 parasites/mm3

Secondary outcome measures

No secondary outcome measures

Overall study start date

20/05/2004

Completion date

17/12/2004

Eligibility

Key inclusion criteria

Children aged over 1 month and under 10 years

Participant type(s)

Patient

Age group

Child

Lower age limit

1 Months

Upper age limit

10 Years

Sex

Both

Target number of participants

600

Total final enrolment

498

Key exclusion criteria

Children with haemoglobin (Hb) <8g/dl who will require iron supplementation

Date of first enrolment

20/05/2004

Date of final enrolment

17/12/2004

Locations

Countries of recruitment

England

Ghana

United Kingdom

Study participating centre Liverpool School of Tropical Medicine

Liverpool United Kingdom L35QA

Sponsor information

Organisation

Liverpool School of Tropical Medicine (UK)

Sponsor details

c/o Dr Martin Donnelly Pembroke Place Liverpool England United Kingdom L35QA

Sponsor type

University/education

Website

http://www.liv.ac.uk/lstm/

ROR

https://ror.org/03svjbs84

Funder(s)

Funder type

Government

Funder Name

The Department for International Development (DfID) Malaria Knowledge Programme of the Liverpool School of Tropical Medicine (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?
Results article	results	01/07/2010	04/06/2019	Yes	No