

Community-effectiveness of the distribution of insecticide-treated bed nets through social marketing antenatal care services in malaria control in rural Burkina Faso

Submission date 16/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/07/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 19/09/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
D4

Study information

Scientific Title

Study objectives

There is the highly controversial question how African programmes can best reach a sustainable high coverage with Insecticide-Treated bed Nets (ITNs) in young children and pregnant women. Against this background a cluster randomised controlled trial is implemented in Nouna Health District in Burkina Faso to compare two different forms of distribution of ITNs.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The protocol has been reviewed and approved by the Ethics Committee of the University of Heidelberg (date: 12 th November 2004, ref: L-357/2004) and the local Ethics Committee in Nouna, Burkina Faso.

Study design

Cluster-randomised controlled trial. Evaluation takes place through annual representative household surveys.

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Malaria

Interventions

Twenty-four peripheral health centres and their catchment areas were randomised to:

1. ITN provision to the general population through social marketing, and
2. ITN provision to the general population through social marketing plus free provision to all pregnant women through antenatal services

The total duration of the intervention will be three years, and participants will be followed up for a further two years.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. ITN coverage in households 12 and 24 months after the start of the interventions
2. ITN use during pregnancy and infancy

Secondary outcome measures

1. Costs per malaria case and per Disability Adjusted Life Years (DALY) prevented
2. Self-reported information on Antenatal Clinic (ANC) visits
3. Insecticide content on ITN and mortality of vector mosquitoes over time
4. Acceptance of health staff and population

Outcomes will be measured at 12 and 24 months after the start of the interventions

Overall study start date

01/08/2006

Completion date

30/12/2008

Eligibility

Key inclusion criteria

Households with children under five years of age.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

sample size: 500 per study arm

Key exclusion criteria

No exclusion criteria.

Date of first enrolment

01/08/2006

Date of final enrolment

30/12/2008

Locations

Countries of recruitment

Burkina Faso

Germany

Study participating centre

Im Neuenheimer Feld 324

Heidelberg

Germany

69120

Sponsor information**Organisation**

University Hospital Heidelberg (Universitätsklinikum Heidelberg) (Germany)

Sponsor details

Im Neuenheimer Feld 672

Heidelberg

Germany

69120

Sponsor type

Hospital/treatment centre

Website

<http://www.klinikum.uni-heidelberg.de/>

ROR

<https://ror.org/013czdx64>

Funder(s)**Funder type**

Research organisation

Funder Name

German Research Foundation (Deutsche Forschungsgemeinschaft [DFG]) (Germany) - Special Research Area of Control of Tropical Infectious Diseases (Sonderforschungsbereich [SFB] 544)

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	11/09/2008		Yes	No