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Insecticide-treated bednets for control of domestic ticks and prevention of African tick-borne relapsing fever

Submission date	Recruitment status	[_] Prospectively registered
14/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/05/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/05/2009	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Philip McCall

Contact details
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
United Kingdom
L3 5QA

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomised controlled trial of insecticide-treated bednets for control of domestic ticks and prevention of African tick-borne relapsing fever

Study objectives
We investigated whether insecticide-treated bednets, using the insecticide formulation and standard practices currently promoted and used widely for malaria prevention in Africa, could control household infestations of soft ticks (Argasids) and prevent transmission of tick-borne relapsing fever (TBRF) to humans.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. The Medical Research Coordinating Committee (MRCC) of the National Institute for Medical Research (NIMRI) Tanzania gave approval on the 24th May 2001 (ref: NIMR/HQ/R.8a/Vol.IX /28)
2. The Research Ethics Committee of the Liverpool School of Tropical Medicine gave approval on the 4th July 2001 (ref: 01.30)

A research permit (03849) was issued by the Tanzanian Committee for Science and Technology (COSTECH), Dar es Salaam, Tanzania on 02/04/2001.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tick-borne relapsing fever (TBRF)

Interventions
This is a randomised controlled trial performed over 29 months; households are selected by two-stage random sampling and randomised to either receive insecticide-treated nets (ITNs) or no nets (control). Households in both arms were unmatched.

Treated households were provided with insecticide-treated bednets: standard green medium-sized circular bednets (1.5 m x 1.8 m at base, 2.1 m high; total net area of 2.7 sq m), of 75-denier polyester fibre (Tanzania manufacturing Textile Limited factory), impregnated with the pyrethroid lambdacyhalothrin (ICONET; Syngenta Crop Protection AG, Basel, Switzerland), using NGAO sachets (dosage of 55.6 mg/m^2) locally marketed for malaria control. Nets were retreated by staff at time of distribution and at 6, 18 and 24 months later.

Control households received no treatment.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Insecticide-treated bednets (impregnated with pyrethroid lambdacyhalothrin)

Primary outcome(s)
Percentages of households infested with O. moubata s.l. (domestic infestations with the soft tick vector of TBRF), numbers of O. moubata s.l. per house (tick-density) and incidence of Borrelia infections in under five year-old children. Surveys were carried out at baseline, with five follow-ups at 3, 7, 15, 18 and 25 months post-intervention.

Key secondary outcome(s))
Using a structured questionnaire, studies on knowledge, attitudes, perceptions and behaviours with regard to the efficacy of ITNs in reducing tick infestations and tick-biting and their perceived benefits were conducted in April 2004 (14 months after the trial began) and at the end of the trial (April 2005). In the latter study, behaviours in the control households and the practice of anti-tick activities were additionally investigated in response to perceived anomalies in the data collected in the previous 12 months.

Completion date
30/04/2005

Eligibility

Key inclusion criteria
All members of families living in traditional style constructed tembe houses (rectangular with a flat roof of sod or earth supported by poles and walls of mud plastered wicker or sun-dried bricks) were eligible for inclusion.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
Families living in households in which floors and walls were plastered with cement and/or roofed with corrugated metal were excluded because it has long been known that they are rarely, if ever, infested with ticks

Date of first enrolment
01/01/2003

Date of final enrolment
30/04/2005

Locations

Countries of recruitment
United Kingdom

England

Tanzania

Study participating centre
Liverpool School of Tropical Medicine
Liverpool
United Kingdom
L3 5QA

Sponsor information

Organisation
Sir Halley Stewart Trust (UK)

ROR
https://ror.org/020w7x032

Funder(s)

Funder type
Charity

Funder Name
Sir Halley Stewart Trust (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	18/10/2003		Yes	No