

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

**Submission date**

14/04/2009

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

13/05/2009

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

13/05/2009

**Condition category**

Infections and Infestations

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Other

## Study type(s)

Treatment

## Participant information sheet

## 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<sup>2</sup>) 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 measure**

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.

**Secondary outcome measures**

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.

**Overall study start date**

01/01/2003

**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

**Age group**

Other

**Sex**

Both

**Target number of participants**

1,472 households

**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**

England

Tanzania

United Kingdom

**Study participating centre**

Liverpool School of Tropical Medicine

Liverpool

United Kingdom

L3 5QA

**Sponsor information****Organisation**

Sir Halley Stewart Trust (UK)

**Sponsor details**

22 Earith Road

Cambridge

United Kingdom

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+44 (0)1954 260707

email@sirhalleystewart.org.uk

**Sponsor type**

Charity

**Website**

<http://www.sirhalleystewart.org.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**

Other non-profit organizations

**Location**

United Kingdom

## 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?
<a href="#">Results article</a>	results	18/10/2003		Yes	No