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Spraying And Nets Towards malaria Elimination

Submission date 27/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/10/2010	**Overall study status** Completed	
Last Edited 08/08/2018	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Steve Lindsay

Contact details
Department of Disease Control
London School of Hygiene & Tropical Medicine
London
United Kingdom
WC1E 7HT
+44 (0)20 7927 2674
Steve.Lindsay@lshtm.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SCC Number 1128, Version 1.0, 17th March 2010

Study information

Scientific Title

Can indoor residual spraying provide additional protection against clinical malaria over current best practice of long-lasting insecticide impregnated nets? A cluster-randomised controlled trial in children in The Gambia

Acronym
SANTE

Study objectives
To evaluate whether there is any benefit against malaria from using indoor residual spraying and long-lasting impregnated nets (LLINs) combined compared to LLINs alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Gambia Government/MRC Laboratories Joint Ethics Committee first approved on the 12th August 2008 (ref: L2009.15, L2010.19; SCC1128)
2. LSHTM Ethics Committee approved on the 16th September 2009 (ref: 5592)

Study design
Two-armed cluster-randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Malaria morbidity and infection

Interventions
1. DDT indoor residual spraying: with rooms sprayed with DDT (2 g/m2), in May/June, at the start of the main malaria transmission season, in 2010 and 2011.
2. Long-lasting insecticidal nets (LLINs): Olyset, permethrin, 2% w/w on polyethylene netting, Sumitomo Chemicals.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Incidence of clinical episodes of malaria presenting at health facilities defined as a child with an axillary temperature of greater than or equal to 37.5°C or a history of fever in the past 48 hours, together with the presence of P. falciparum parasites of any density detected by microscopy and /or RDT in the absence of other detectable cause of fever.

Secondary outcome measures
1. Mean haemoglobin concentration in children in the two study arms measured in the end of the transmission season survey
2. Parasite prevalence in children in the two study arms measured at the end of the transmission season

Overall study start date
01/03/2010

Completion date
30/04/2012

Eligibility

Key inclusion criteria
1. No distinctions will be made regarding gender or ethnic group
2. Children (aged 6 months - 13 years old) whose parents/carers give written, informed consent for their child
3. Eligible children greater than 6 years old will also be explained the purpose of the study and what is required according to their capability
4. In the case of school age children, only those who live in their village during term-time

In order for the results from this study to be as generalisable as possible, no distinctions will be made in terms of medical condition or physical health.

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
13 Years

Sex
Both

Target number of participants

Approximately 7,700 children

Key exclusion criteria
1. Children for whom informed consent is not or cannot be provided
2. Aged under 6 months or over 13 years on 1st June for the year of survey
3. Expected to be non-residence during several months of the transmission season

Date of first enrolment
01/03/2010

Date of final enrolment
30/04/2012

Locations

Countries of recruitment
England

Gambia

United Kingdom

Study participating centre
Department of Disease Control
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation
Medical Research Council Laboratories (Gambia)

Sponsor details
Atlantic Road
PO Box 273 Banju
Fajara
Gambia
-
(+220) 449 5442/6 ext. 2308
scc@mrc.gm

Sponsor type
Research council

Website
http://www.mrc.gm/

ROR
https://ror.org/025wfj672

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK) (ref: SSC 1128)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

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?
Results article	results	10/06/2011		Yes	No
Results article	results	11/04/2015		Yes	No
	results				

Results article	06/08/2018	Yes	No