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Spraying And Nets Towards malaria Elimination

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Prevention

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(s)
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.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
13 years

Sex
All

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
United Kingdom

England

Gambia

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

Sponsor information

Organisation
Medical Research Council Laboratories (Gambia)

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

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 article	results	06/08/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes