ISRCTN42288908 https://doi.org/10.1186/ISRCTN42288908

Household-wide treatment for the control of head lice infestations in an impoverished community

Submission date	Recruitment status	[_] Prospectively registered
09/05/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/05/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/05/2009	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Hermann Feldmeier

Contact details
Institut for Microbiology and Hygiene
Charite-University Medicine Berlin
Campus Benjamin Franklin
Hindenburgdamm 27
Berlin
Germany
12203

Additional identifiers

Study information

Scientific Title
Impact of household-wide treatment for the control of head lice infestations in an impoverished community: a randomised observer-blinded controlled trial

Study objectives

Children of families that had received household-wide head lice treatment with ivermectin remain longer without head lice infestation than children of families without treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Board of the Federal University of Ceará approved on the 14th September 2006 (ref: 179/06). Registered in the database of the Brazilian Ministry of Health for studies involving human subjects.

Primary study design
Interventional

Study design
Randomised observer-blind controlled trial (single-centre)

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Active head lice infestation

Interventions
Participants (sentinels) were recruted in a holiday resort outside the endemic area where another trial had taken place immediately before the study. While still in the holiday resort but immediately before entering the study, participants had received oral ivermectin. In addition, baseline head lice status was assessed by vigorous wet-combing.

Households of the participating children were randomised into two groups. In the intervention group, all household members (except the head lice-free sentinels) were treated orally with ivermectin (200 µg/kg; Revectina®, Solvay Farma, Brazil) the day before the sentinels returned to their families. Treatment was repeated after 10 days. Household members of the control group remained untreated. A day after the household-wide treatment the sentinels returned from the holiday resort and were examined for the presence of head lice by wet combing every three to four days, during a period of 60 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Ivermectin

Primary outcome(s)
The median infestation-free period, defined as the days between baseline and the first head lice positive examination during follow-up visits. A positive head lice examination was defined as the detection of at least one viable head louse or nymph determined by diagnostic wet-combing.

Key secondary outcome(s)
Analyses on individual characteristics (sex, hair length and type) and characteristics of the households (poverty, crowding) were done to measure their importance for infestation-free periods. The annual incidence was calculated/estimated.

Completion date
31/03/2007

Eligibility

Key inclusion criteria
1. Children aged 5 - 15 years, either sex
2. Absence of active head lice infestation determined by diagnostic wet-combing
3. Written consent obtained from the study participants and carers

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
15 Years

Sex
All

Key exclusion criteria
1. Active head lice infestation during baseline examination (defined as the detection of at least one viable head louse or nymph after vigorous wet-combing)
2. Absence from the study area for more than a week
3. Unwillingess to participate in the study

Date of first enrolment
01/02/2007

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
Brazil

Germany

Study participating centre
Institut for Microbiology and Hygiene
Berlin
Germany
12203

Sponsor information

Organisation
Mandacaru Foundation (Brazil)

ROR
https://ror.org/05h876969

Funder(s)

Funder type
Charity

Funder Name
Mandacaru Foundation (Brazil)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration