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# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# 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.

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

### 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
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 measure
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.

### Secondary outcome measures
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.

### Overall study start date
01/02/2007

### 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

### Age group
Child

### Lower age limit
5 Years

### Upper age limit
15 Years

### Sex
Both

### Target number of participants
132

### 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
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## Sponsor information

### Organisation
Mandacaru Foundation (Brazil)

### Sponsor details
Rua José Vilar de Andrade 257
Fortaleza
Brazil
CE 60833-830

### Sponsor type
Charity

### Website
http://www.mandacaru-foundation.org

**ROR**
https://ror.org/05h876969

# Funder(s)

**Funder type**
Charity

**Funder Name**
Mandacaru Foundation (Brazil)

# 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