

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

Submission date
09/05/2009

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
29/05/2009

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
29/05/2009

Condition category
Infections and Infestations

☐ Individual participant data

☐ 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

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 recruited 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. Unwillingness 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)

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