ISRCTN15117709 https://doi.org/10.1186/ISRCTN15117709

Efficacy of a new head lice treatment based on silicon oil

Submission date	Recruitment status	[_] Prospectively registered
02/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/10/2008	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CAAE - 1422.0.000.040-06 179/06

Study information

Scientific Title
Efficacy of a pediculicide based on dimeticone: randomised observer-blinded comparative trial in patients with severe infestation

Acronym
DIMPED (DIMeticone for the treatment of PEDiculosis)

Study objectives
The efficacy against head lice infestation of a product containing a high (92%) concentration of the silicon oil dimeticone (similar to Nyda®) is similar or superior to a product containing 1% permethrin.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethical Review Board of the Federal University of Ceará (Brazil) on the 14th September 2006 (ref: 179/06). Registered in the database of the Brazilian Ministry of Health for studies involving human subjects (Sistema Nacional de Informações Sobre Ética em Pesquisa envolvendo Seres Humanos [SISNEP]), accessible under http://portal.saude.gov.br/sisnep/pesquisador/ (project no: 1422.0.000.040-06).

Study design
Randomised, controlled, observer-blinded clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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

Interventions
Participants were recruited from a poor urban neighbourhood in Brazil where head lice are highly prevalent. To minimise reinfestation during the trial, study participants were transferred to a holiday resort outside the endemic area for a period of nine days.

Participants were randomised to receive either topical treatment with a product containing a high percentage of dimeticones (92%), equivalent in composition to Nyda® (G. Pohl-Boskamp GmbH & Co. KG, Hohenlockstedt, Germany), or topical permethrin 1% aqueous solution (Kwell®, GlaxoSmithKline, Brazil). Two topical applications were done, seven days apart. Participants

were treated immediately upon arrival at the resort (day 1) and, a second time seven days later (day 8) to kill newly hatched lice from eggs which may have survived the first treatment.

The products were used according to the producers' recommendations. The fine tooth comb provided by both producers together with the pediculicide was not used after the topical application of the products. The dimeticone-based product was applied to dry hair and then left to dry naturally. After eight hours the hair was washed with a commercial shampoo not containing dimeticones. Kwell® was applied to wet hair, left for 30 minutes and thereafter washed out in an identical manner as the other product. Both products were applied systematically onto the hair from the hair shafts to the tips, and a normal comb was used to spread the liquids evenly.

The dimeticon-based product (in composition similar to Nyda® , G. Pohl-Boskamp GmbH & Co. KG, Hohenlockstedt, Germany) was prepared at the Department of Pharmacy of the Federal University of Ceará by an experienced pharmacist, the permethrin product bought locally at a pharmacy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dimeticone product equivalent in composition to Nyda®, topical permethrin

Primary outcome measure
The primary outcome measure was defined as the proportion of participants cured of head lice infestation one, six and eight days after the first treatment (i.e. days 2, 7 and 9, respectively). Cure was defined as the complete absence of viable lice on the scalp, as determined by wet combing with a high quality plastic head louse comb.

Secondary outcome measures
1. Reduction of clinical pathology: days 1 (before intervention), 2, 4, 7 and 9
2. Reduction of the degree of itching (assessed based on a pre-tested ordinal Visual Analogue Scale [VAS] ranging from 0 to 4): days 1 (before intervention), 2, 3, 4, 5, 6, 7, 8 and 9
3. Cosmetic acceptability of the products, assessed using a summary score ranging from -4 (extremely negative) to +4 (extremely positive), with a standardised questionnaire including subjective assessment of smelling, irritation of scalp, cosmetic changes of hair, and changes in the easiness to comb the hair: days 2, 4, 7 and 9
4. Safety (number and type of adverse events). Clinical pathology included the presence of erythema, papules, excoriations, eczema, secondary infection and enlarged cervical or retro-auricular lymph nodes: days 2, 4, 7 and 9 (and continuous documentation when any adverse event [AE] occurred, indendent from timepoints).

Overall study start date
02/01/2007

Completion date
31/01/2007

Eligibility

Key inclusion criteria
1. Children aged 5 - 15 years, either sex
2. An active head lice infestation (one or more active head lice found after three minutes of visual inspection)
3. Written consent obtained from 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
146 children and adolescents

Key exclusion criteria
1. Use of head lice products, anthelminthics, or antibiotics within the previous four weeks
2. Severe skin disorders of the scalp (such as generalised impetigo, eczema, psoriasis or chronic dermatitis of unknown origin)
3. Bleached or colour treated hair within the previous four weeks
4. Known sensitivity to any ingredients in the products
5. Mental disease
6. Drug abuse
7. Pregnant or lactating girls
8. Unwillingness to stay for nine days in a holiday resort outside the endemic area where the clinical trial would be carried out
9. Participation in another clinical study in the previous month

Date of first enrolment
02/01/2007

Date of final enrolment
31/01/2007

Locations

Countries of recruitment
Brazil

Study participating centre
Departamento de Saúde Comunitária
Fortaleza
Brazil
60430-140

Sponsor information

Organisation
Mandacaru Foundation (Brazil)

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Rua José Vilar de Andrade 257
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Sponsor type
Research organisation

ROR
https://ror.org/05h876969

Funder(s)

Funder type
Research organisation

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results:	10/09/2008		Yes	No