

A randomised, controlled, assessor-blind, clinical trial to demonstrate superiority of Hedrin 4% dimeticone lotion compared with Derbac-M 0.5% malathion aqueous liquid in the treatment of head lice

Submission date

05/12/2006

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

27/12/2006

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

11/11/2008

Condition category

Infections and Infestations

☐ Individual participant data

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

2006-004136-73

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CTMK05

Study information

Scientific Title

Study objectives

Is Hedrin 4% lotion more effective than Derbac-M liquid in the treatment of head louse infestation?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Hertfordshire 1 Research Ethics Committee reviewed 14 August 2006 (ref.: 06/Q0201/52).

Study design

A randomised, controlled, assessor-blind, parallel group clinical trial.

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

Head louse infestation

Interventions

Dimeticone 4% lotion (Hedrin 4% lotion): The product will be applied directly to dry hair. Sufficient product will be applied to saturate the hair and scalp. The product will be left in place for eight hours (or overnight) before being shampooed and rinsed off with water. The product will be reapplied at day seven.

Malathion 0.5% aqueous emulsion (Derbac-M liquid): The product will be applied directly to dry hair. Sufficient product will be applied to saturate the hair and scalp. The product will be left in

place for eight hours (or overnight) before being shampooed and rinsed off with water. The product will be reapplied at day seven.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Hedrin and Derbac-M

Primary outcome measure

To compare the efficacy of Hedrin 4% lotion against Derbac-M liquid in the eradication of head lice.

Secondary outcome measures

To compare Hedrin 4% lotion against Derbac-M liquid for safety, ease of use, and participant acceptability.

Overall study start date

01/10/2006

Completion date

31/12/2006

Eligibility

Key inclusion criteria

1. Participants aged six months and over with no upper age limit
2. Participants who, upon examination, are confirmed to have live head lice
3. Participants who give written informed consent, or if the participant is under 16 years of age whose parent/guardian gives written informed consent to participate in the study
4. Participants who will be available for home visits by Medical Entomology Centre (MEC) study team members over the 14 days following first treatment

Participant type(s)

Patient

Age group

Other

Sex

Not Specified

Target number of participants

58 children and 15 adults

Key exclusion criteria

1. Participants with a known sensitivity to any of the ingredients in Hedrin 4% lotion or Derbac-M liquid
2. Participants with a secondary bacterial infection of the scalp (e.g. impetigo) or who have a long-term scalp condition (e.g. psoriasis of the scalp)
3. Participants who have been treated with other head lice products within the previous two weeks
4. Participants who have bleached hair, or hair that has been colour treated or permanently waved within the previous four weeks (wash in/wash out colours are acceptable)
5. Participants who have been treated with the antibiotics Co-Trimoxazole, Septrin or Trimethoprim within the previous four weeks, or who are currently taking such a course
6. Pregnant or nursing mothers
7. Participants who have participated in another clinical study within one month before entry to this study
8. Participants who have already participated in this clinical study

Date of first enrolment

01/10/2006

Date of final enrolment

31/12/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Medical Entomology Centre**

Royston

United Kingdom

SG8 6QZ

Sponsor information

Organisation

Thornton & Ross Ltd (UK)

Sponsor details

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Sponsor type
Industry

Website
<http://www.thorntonross.com/>

ROR
<https://ror.org/00frd0c49>

Funder(s)

Funder type
Industry

Funder Name
Thornton & Ross Ltd (UK)

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	07/11/2007		Yes	No