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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	Recruitment status	[_] Prospectively registered
05/12/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/11/2008	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
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