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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**
05/12/2006

**Registration date**
27/12/2006

**Last Edited**
11/11/2008

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

**Clinical Trials Information System (CTIS)**
2006-004136-73

**Protocol serial number**
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).

**Primary study design**
Interventional

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

**Study type(s)**
Treatment

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

### Key secondary outcome(s)
To compare Hedrin 4% lotion against Derbac-M liquid for safety, ease of use, and participant acceptability.

### 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

### Healthy volunteers allowed
No

### Age group
Other

### Sex
Not Specified

### 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**
United Kingdom

England

**Study participating centre**
**Medical Entomology Centre**
Royston
United Kingdom
SG8 6QZ

# Sponsor information

**Organisation**
Thornton & Ross Ltd (UK)

**ROR**
https://ror.org/00frd0c49

# Funder(s)

**Funder type**
Industry

**Funder Name**
Thornton & Ross Ltd (UK)

# Results and Publications

**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 |