

A proof of concept clinical investigation to evaluate the activity of Hedrin® liquid gel in the treatment of head lice using a 15 minutes application time

Submission date 04/11/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/12/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 18/03/2013	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

We know from a previous study that Hedrin 4% gel works with a 1 hour application time. The aim of this study is to find out whether that Hedrin 4% gel works just as well to eliminate head louse infestation using just a 15 minutes application.

Who can participate?

The study is open to anyone who has head lice over the age of 6 months and who fits the other entry criteria.

What does the study involve?

The study first involves checking for presence of lice. If you then wish to take part we shall ask you (or your carer) to sign a consent form after which we can apply the treatment. A second application of the treatment product is applied after 7 days to eliminate any young lice that emerge from eggs during that first week. We shall check the safety and acceptability of the treatment and the progress of the effectiveness when we comb everyone looking for lice twice between treatments, on days 1 and 6 after first treatment, and then twice after the second treatment on days 9 and 14. Anyone who has lice after the second treatment will be provided with a different treatment (Hedrin 4% lotion) to eliminate the infestation.

What are the possible benefits and risks of participating?

We hope everyone who takes part will have their head lice eliminated.

Where is the study run from?

The study will be conducted in and around Cambridgeshire by the Medical Entomology Centre based just outside Cambridge. Our team of investigators will visit you at home to run all the procedures so you don't need to go anywhere.

When is the study starting and how long is it expected to run for?
The study starts in January 2010 and will run until about the end of May 2010.

Who is funding the study?
It is being funded by Thornton & Ross Ltd, the makers of Hedrin 4% lotion.

Who is the main contact?
The main contact for the study is Elizabeth Brunton at the Medical Entomology Centre.

Contact information

Type(s)
Scientific

Contact name
Mr Ian Burgess

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CTMK10

Study information

Scientific Title
A proof of concept clinical investigation to evaluate the activity of Hedrin® liquid gel in the treatment of head lice using a 15 minutes application time: a single-centre non-randomised single-arm proof of concept study

Study objectives
To determine whether Hedrin® liquid gel is effective using a 15 minutes application in the eradication of head lice, and to evaluate the treatment regimen with regard to safety, ease of application, ease of washing, and participant acceptability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single-centre non-randomised single-arm proof of concept study

Primary study design

Interventional

Secondary study design

Non randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Head louse infestation

Interventions

All participants will receive the following intervention (single-arm trial): 15 minutes application of dimeticone 4% (Hedrin® liquid gel), on day 0 (at enrolment) and day 7. Patients will be followed up for 14 days from day 0.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Dimeticone (Hedrin® liquid gel)

Primary outcome measure

Cure of infestation, defined as no evidence of head lice, assessed between completion of the second application of treatment on day 7 and day 14 (the first treatment being applied on day 0).

Secondary outcome measures

1. Prevention of louse egg hatching (ovicidal action), defined as no 1st and 2nd stage nymphs found at assessments during the week following the first treatment or after the second application of treatment

2. Safety of the product monitored by observation for adverse events on days 0, 1, 6, 7, 9, and 14 of the study
3. Ease of use by investigators, assessed by a questionnaire on the day of the first treatment
4. Ease of washing from the hair, assessed by a participant questionnaire at the final assessment on day 14
5. Participant acceptability, assessed by a questionnaire at the final assessment on day 14

Overall study start date

20/01/2010

Completion date

30/04/2010

Eligibility

Key inclusion criteria

1. Both males and females, aged 6 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 11 years of age whose parent/guardian gives written informed consent to participate in the study
4. Participants who will be available for follow-up visits by study team members over the 14 days following first treatment

Participant type(s)

Patient

Age group

Other

Sex

Both

Target number of participants

40

Key exclusion criteria

1. Participants with a known sensitivity to any of the ingredients in Hedrin® liquid gel
2. Participants with a secondary bacterial infection of the scalp (e.g. impetigo) or who have an active 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 permanently waved within the previous four weeks
5. Participants who have been treated with the antibiotics co-trimoxazole 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 1 month before entry to this study
8. Participants who have already participated in this clinical study

Date of first enrolment

20/01/2010

Date of final enrolment

30/04/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Medical Entomology Centre

Cambridge

United Kingdom

CB25 9AU

Sponsor information

Organisation

Thornton & Ross Ltd (UK)

Sponsor details

Linthwaite

Huddersfield

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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	25/01/2011		Yes	No