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A proof of concept clinical investigation to evaluate the activity of Hedrin® 4% gel in the treatment of head lice using a 1-hour application time

Submission date
09/02/2009

Recruitment status
No longer recruiting

Registration date
13/03/2009

Overall study status
Completed

Last Edited
16/05/2018

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims.
We know from a previous study that Hedrin 4% lotion is effective with a 1 hour application time. The aim of this study is to confirm that Hedrin 4% gel, a more viscous version of the product that should be easier to use, works just as well to eliminate head louse infestation.

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 the area of 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 dont need to go anywhere.

When is the study starting and how long is it expected to run for?
The study starts in April or May 2009 and will run until about the end of July 2009.

Who is funding the study?
Thornton & Ross Ltd, the makers of Hedrin 4% lotion

Who is the main contact?
Elizabeth Brunton

Contact information

Type(s)
Scientific

Contact name
Mr Ian Burgess

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Additional identifiers

Protocol serial number
CTMK09

Study information

Scientific Title
A proof of concept clinical investigation to evaluate the activity of Hedrin® 4% gel in the treatment of head lice using a 1-hour application time: a single-centre non-randomised single-arm proof of concept study

Study objectives
To determine whether Hedrin® 4% gel is effective using a 1-hour 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)

South West Research Ethics Committee, 03/04/2009, ref: 09/H0206/16

Primary study design
Interventional

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

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Head louse infestation

Interventions
All participants will received the following intervention (single-arm trial):
One-hour application of dimeticone 4% (Hedrin® 4%) gel, on day zero (at enrolment) and day 7.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Hedrin® 4% gel

Primary outcome(s)
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).

Key secondary outcome(s)
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

Completion date
01/07/2009

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 16 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

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Participants with a known sensitivity to any of the ingredients in Hedrin® 4% 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
20/04/2009

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Medical Entomology Centre
Cambridge
United Kingdom
CB25 9AU

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
Participant level data are currently not available in the public domain and await approval for release from the sponsor, Thornton & Ross Ltd. At such time as the data may be released in the future they will be available from Ian Burgess (ian@insectreseach.com). These anonymised spreadsheet data will comprise demographic data and outcome data from individual follow-up examinations. Consent for dissemination in appropriate scientific studies was obtained at the time of enrolment.

IPD sharing plan summary
Available on request