ISRCTN95412572 https://doi.org/10.1186/ISRCTN95412572

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

Submission date
11/11/2008

Recruitment status
No longer recruiting

Registration date
01/12/2008

Overall study status
Completed

Last Edited
06/07/2016

Condition category
Infections and Infestations

[_] 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 previous studies that Hedrin 4% lotion is effective with an 8 hour application time and reasonably effective with a 20 minutes application. The aim of this study is to confirm that Hedrin 4% lotion works just as well to eliminate head louse infestation using it for 1 hour.

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 8 hours application) 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 November 2008 and will run until about the end of February 2009.

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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Contact details
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Additional identifiers

EudraCT/CTIS number
2008-005787-13

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CTMK08

Study information

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

Study objectives
To determine whether Hedrin® 4% lotion can be used for a shorter application time (1 hour) in the eradication of head lice than the currently approved overnight application, and to evaluate the treatment regimen with regard to safety, ease of application, and participant acceptability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Essex 1 Research Ethics Committee, approved on 27/10/2008 (ref: 08/H0301/114)

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)
Not specified

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 received the following intervention (single-arm trial):

One-hour application of dimeticone 4% (Hedrin® 4%) lotion, on day zero (at enrolment) and day 7.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Dimeticone (Hedrin®)

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
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. Participant acceptability, assessed by a questionnaire at the final assessment on day 14

Overall study start date
17/11/2008

Completion date
31/01/2009

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

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® 4% lotion
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
17/11/2008

Date of final enrolment
31/01/2009

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
United Kingdom
HD7 5QH

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
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No