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Can we prevent head lice?

Submission date
10/10/2012

Recruitment status
No longer recruiting

Registration date
19/10/2012

Overall study status
Completed

Last Edited
26/04/2016

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Head lice are still common in Britain despite the introduction of treatments that are not affected by resistance. This is mainly because not everyone treats the infestation at the same time. So many people would like to have a product that helps prevent infestations from arising. This study is to test a product designed to stop lice from establishing an infestation.

Who can participate?
This study is for the youngest person attending school from each household taking part who is at risk of head louse infestation. So the youngest will be 4 years old but there is no upper age limit otherwise.

What does the study involve?
If you fit the enrolment requirements you will first be treated on two occasions to make sure you dont have head lice, using Hedrin Once.
There are two study treatments. One is the active product (1% octanediol solution). This has the same active material as Hedrin Treat & Go but at a lower concentration, which has been shown to kill lice. The other product is a placebo (no active ingredient) that has the same appearance. Both products are used like a regular detangler and leave in conditioner spray. They need to be applied at least twice each week or, if you wash your hear more often, applied after each hair wash.
Everyone taking part will be randomly allocated to receive one of the treatments at the start of the study. They will use that product for 6 weeks. During that time one of our team will visit once each week to check for lice. If we find just one or two we will not do anything immediately because the active product takes a little while to take effect and the lice could have just arrived. However, at the next visit, if we find lice, we shall treat using Hedrin Once. At any time if we find newly hatched baby lice or more than five lice of any size we shall also treat using Hedrin Once. After the treatment you will continue with the same product until the end of the 6 week period. At the end of 6 weeks everyone will be treated again using Hedrin Once to make sure they have no lice again. After that they will change to the other treatment for 6 weeks, so everyone on the study will use both treatments. Because the bottles will be just labeled A or B neither the investigators nor the people using them will know which product is which.
Any other members of the family who catch lice during the course of the study will also be able to have a treatment to get rid of their lice while the study is running.

What are the possible benefits and risks of participating?
If the active product works as well as hope you should be protected from head louse infestation during the period you are using it. Also, at any time during the study, if you or family members catch lice they can be treated.
There are no known risks involved with this treatment, although some people may find their scalp is dryer than normal if they use too much product.

Where is the study run from?
The study is run by the Medical Entomology Centre in Cambridge.

When is study starting and how long is it expected to run for?
The study is starting in mid-October 2012 and will run until later February 2013, with a short break over the Christmas holiday period.

Who is funding the study?
The study is funded by Thornton & Ross Ltd, the makers of the Hedrin range of head louse treatment products.

Who is the main contact?
Ian Burgess, ian@insectresearch.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CTMK15

Study information

Scientific Title
A randomised, double-blind, cross-over, placebo controlled clinical trial to demonstrate the proof of concept for a product designed to protect against development of head louse infestation

Study objectives
To demonstrate the proof of concept that Octanediol 1% Solution is effective to limit the risk of development/growth of an infestation with head lice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Northern & Yorkshire approved on 1st August 2012 , ref 12/NE /0253

Study design
Randomised double-blind cross-over placebo controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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 be treated using 4% dimeticone gel on two occasions a week apart before starting on study treatments to eliminate any current infestation.

1. 1% 1,2-Octanediol solution

2. Placebo

Both preparations are applied in the same manner as detangling leave in conditioner sprays. Treatment is applied a minimum of twice each week or following every hair wash.

Participants receive one blinded treatment (either active or placebo) following the initial elimination of infestation. They continue for 6 weeks using the same treatment. After the 6 week period they are again treated using 4% dimeticone gel to eliminate any infestation not identified by investigators. They then change to the other blinded treatment, i.e. those on placebo change to active and vice versa.

If at any time during the study an active infestation is identified a further course of treatment using 4% dimeticone gel is instituted.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Comparison of effectiveness of Octanediol 1% Solution, applied at least twice each week, compared with placebo to prevent or limit establishment of head louse infestation as measured by the time to first infestation with head lice during either of the six week periods on treatment.

Secondary outcome measures
1. Whether an infestation occurred during the six week period
2. The number of infestations occurring during the period, the safety of the product

Overall study start date
22/10/2012

Completion date
28/02/2013

Eligibility

Key inclusion criteria
1. Both males and females attending school with no upper age limit, although they must be the youngest qualifying member of the household
2. People who are confirmed to be at risk of infestation with head lice
3. People 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. People who will be available for home visits by study team members over the 14 weeks of the study

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
68 with only one participant per household, that person being the youngest eligible individual attending school

Key exclusion criteria
1. People with a known sensitivity to any of the ingredients in Octanediol 1% Solution, Hedrin Once liquid gel or the placebo leave in conditioner preparation
2. People 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. Pregnant or nursing mothers
4. People who have participated in another clinical study within 1 month before entry to this study
5. People who have already participated in this clinical study

Date of first enrolment
22/10/2012

Date of final enrolment
28/02/2013

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 Laboratories
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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, Huddersfield (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	30/05/2014		Yes	No