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Is Hedrin® 4% lotion Dev 42 more effective than Hedrin® 4% lotion against head louse eggs?

Submission date
09/03/2009

Recruitment status
No longer recruiting

Registration date
19/03/2009

Overall study status
Completed

Last Edited
30/03/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
We know from previous studies that Hedrin 4% lotion gets rid of a head louse infestation. The aim of this study is to compare Hedrin 4% lotion with a modified version of the product to see if the alternative is more effective to cure head louse infestation.

Who can participate?
The study will be conducted in two schools but is open to anyone in the villages serving those schools who has head lice and is 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, 2 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 further 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 the schools of Maldan and Osmancali, two villages in Manisa province, Turkey. Our team of investigators will first visit the schools to identify students with lice and then visit them at home to run all the procedures.

When is the study starting and how long is it expected to run for?
The study was carried out in April and May of 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 Dr Özgür Kurt of Celal Bayar University School of Medicine.

Contact information

Type(s)
Scientific

Contact name
Mr Ian Burgess

Contact details
Medical Entomology Centre
Insect Research & Development Limited
6 Quy Court
Colliers Lane
Stow-cum-Quy
Cambridge
United Kingdom
CB25 9AU
+44 (0)1223 810070
ian@insectresearch.com

Additional identifiers

Protocol serial number
CTMK06

Study information

Scientific Title
A randomised, controlled, assessor-blind, clinical trial to compare Hedrin® 4% dimeticone lotion with Hedrin® 4% lotion Dev 42 in the treatment of head lice

Study objectives
To compare efficacy of Hedrin® 4% lotion with Hedrin® 4% lotion Dev 42 in the eradication of head lice, to compare the products for ovicidal activity, and to compare the products for safety, ease of application and participant acceptability.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Medical Faculty, Celal Bayar University gave approval on the 25th February 2008 (ref: 25)

Study design

Randomised controlled assessor blinded parallel group study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
1. Dimeticone 4% lotion (Hedrin® 4% lotion)
2. Dimeticone 4% lotion, alternative mixture (Hedrin® 4% lotion Dev 42)

Both products 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. Treatments were applied on days 0 and 7 and post-treatment assessments were conducted on days 1, 2, 6, 9, 14.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Hedrin® 4% lotion Dev 42, Hedrin® 4% lotion

Primary outcome(s)
1. To compare Hedrin® 4% lotion with Hedrin® 4% lotion Dev 42 with regard to inhibition of hatching of louse eggs (ovicidal activity): no nymphal lice emerging from eggs between treatments (i.e. on day 1, 2, or 6) or after the second treatment
2. To compare the efficacy of Hedrin® 4% lotion with Hedrin® 4% lotion Dev 42 with regard to the eradication of head lice: assessed post-second treatment, i.e. no lice on days 9 or 14

Key secondary outcome(s))
To compare Hedrin® 4% lotion with Hedrin® 4% lotion Dev 42 with regard to safety, ease of application and participant acceptability, assessments made on days 0 and 7 post-treatment application and at each of the efficacy assessments on days 1, 2, 6, 9, and 14

Completion date
31/05/2008

Eligibility

Key inclusion criteria
1. Both males and females, aged 4 years 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
Other

Sex
All

Total final enrolment
72

Key exclusion criteria
1. Participants with a known sensitivity to any of the ingredients in Hedrin® 4% lotion or Hedrin® 4% lotion Dev 42
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
01/04/2008

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
United Kingdom

England

Türkiye

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

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	01/12/2009	30/03/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes