

Hedrin® Once vs Lyclear® against head lice

Submission date 19/04/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/08/2013	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CTMK13

Study information

Scientific Title

A randomised, controlled, assessor-blind, clinical trial to demonstrate superiority of Hedrin® Once liquid gel compared with Lyclear® 1% permethrin creme rinse in the treatment of head lice

Study objectives

To confirm that Hedrin® Once is effective to kill head lice and their eggs with a single application, in comparison with two applications of Lyclear® and to identify any significant difference in performance (superiority) of one product over the other in the eradication of head lice.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Central London Research Ethics Committee 2 to be reviewed on the 04/05/2011 (ref: 11/LO/0455) - Approval pending as of 19/04/2011

Study design

Single-centre randomised two-arm comparative study

Primary study design

Interventional

Secondary study design

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

Group A: Hedrin® Once liquid gel , applied for 15 minutes before washing off using shampoo, applied one one occasion only.

Group B: Lyclear® 1% permethrin creme rinse, applied for 10 minutes to pre-washed and towel dried hair before rinsing off with water, with a repeat treatment one week later.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Hedrin® Once liquid gel, Lynclear® 1%

Primary outcome measure

1. To demonstrate cure of infestation, defined as no evidence of head lice.
 - 1.1. For Hedrin® Once following a single 15 minute application up to day 14
 - 1.2. For Lynclear® creme rinse using two applications assessed between completion of the second application of treatment on day 7 and day 14 (the first treatment for both products being applied on day 0).

Secondary outcome measures

1. To compare the efficacy of Hedrin® Once with Lynclear® creme rinse and to identify superiority of one product over the other if appropriate.
2. Safety of the products monitored by observation for adverse events on days 0, 1, 6, 7, 9, and 14 of the study

Overall study start date

01/06/2011

Completion date

31/10/2011

Eligibility

Key inclusion criteria

1. Both males and females, aged 6 months and over with no upper age limit
2. People who upon examination, are confirmed to have live 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 follow-up visits by study team members over the 14 days following first treatment

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

84 (randomised by household) from an estimated 44 households, divided into two groups of 42

Key exclusion criteria

1. Participants with a known sensitivity to any of the ingredients in Hedrin® Once liquid gel or Lynclear® 1% permethrin creme rinse, pyrethroid insecticides, or plants related to dandelions or

chrysanthemums.

2. People 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. People who have been treated with other head lice products within the previous two weeks
4. People who have bleached hair, or hair that has been permanently waved within the previous four weeks
5. People 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. People who have participated in another clinical study within one month before entry to this study
8. People who have already participated in this clinical study

Date of first enrolment

01/06/2011

Date of final enrolment

31/10/2011

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>

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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	01/04/2013		Yes	No
HRA research summary			28/06/2023	No	No