# Hedrin® Once vs Lyclear® against head lice

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
19/04/2011		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
24/05/2011	Completed	[X] Results		
<b>Last Edited</b> 27/08/2013	Condition category	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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# Additional identifiers

# Protocol serial number

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

### Study type(s)

Treatment

### 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, Lyclear® 1%

### Primary outcome(s)

- 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 Lyclear® 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).

### Key secondary outcome(s))

- 1. To compare the efficacy of Hedrin® Once with Lyclear® 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

### 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/quardian 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** 

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Key exclusion criteria

- 1. Participants with a known sensitivity to any of the ingredients in Hedrin® Once liquid gel or Lyclear® 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

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

## 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes