ISRCTN88144046 https://doi.org/10.1186/ISRCTN88144046

Hedrin® Once vs Lyclear® against head lice

Submission date	Recruitment status	[X] Prospectively registered
19/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/08/2013	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Ian F 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)122 381 0070
ian@insectresearch.com

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/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

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