

Does Lyclear® spray away work better than permethrin to cure head lice?

Submission date 07/04/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 29/05/2008	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 13/09/2017	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CTOM01, version 1.3 (18/02/2008)

Study information

Scientific Title

A randomised, controlled, assessor-blind, clinical trial to investigate superiority of Lyclear® spray away (ParaNix® spray) compared with Infectopedicul® permethrin 0.5% lotion in the treatment of head lice

Study objectives

To investigate superiority of Lyclear® spray away (ParaNix® spray) over Infectopedicul® in the eradication of head lice and prevention of hatching of louse eggs and to compare the products for safety, ease of application and participant acceptability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (West) Research Ethics Committee. Date of approval: 04/03/2008 (ref: 08/H1307/18)

Primary study design

Interventional

Study design

Randomised, controlled, assessor blind, parallel group study.

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Infestation with head lice (*Pediculus capitis*)

Interventions

The participants will be randomly allocated to the two groups in equal numbers.

Group 1: Participants will be treated with Lyclear® spray away (ParaNix® spray; topical) containing:

Active: *Illicium verum* (star anise) oil, caprylic/capric triglyceride (fractionated coconut oil derivative), *cananga odorata* (ylang-ylang) oil

Excipients: Propan-2-ol

Group 2: Participants will be treated with Infectopedicul® lotion (topical) containing:

Active: 0.5% permethrin

Excipients: Ethanol, propanol-2-ol, water, propylene glycol, sodium hydrogen phosphate

The total duration of intervention and follow-up for each participant is 15 days, two treatments 9 days apart with a follow-up 2 and 7 days after the first treatment and 2 and 5 days after the second treatment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Permethrin

Primary outcome(s)

1. Number of participants with no evidence of active head louse infestation 14 days (+/- 1 day) after enrolment
2. Safety, assessed 2 and 7 days after the first treatment, and 2 and 5 days after the second treatment

Key secondary outcome(s)

1. Ease of application (investigator opinion), assessed using a questionnaire on the same day as the first treatment
2. Participant acceptability, assessed using a questionnaire 5 days after the second treatment

Completion date

31/05/2008

Eligibility

Key inclusion criteria

1. Both males and females, aged 2 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 home visits by Medical Entomology Centre (MEC) study team members over the 14 days following first treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

All

Key exclusion criteria

1. Participants with a known sensitivity to any of the ingredients in Lyclear® spray away (ParaNix® spray) or Infectopedicul® lotion
2. Participants with asthma or a similar respiratory condition
3. Participants 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)
4. Participants who have been treated with other head lice products within the previous two weeks
5. Participants who have bleached hair, or hair that has been colour treated or permanently waved within the previous four weeks (wash in/wash out colours are acceptable)
6. 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

- 7. Pregnant or nursing mothers
- 8. Participants who have participated in another clinical study within 1 month before entry to this study
- 9. Participants who have already participated in this clinical study

Date of first enrolment

23/03/2008

Date of final enrolment

31/05/2008

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Medical Entomology Centre

Royston

United Kingdom

SG8 6QZ

Sponsor information

Organisation

Omega Pharma N.V. (Belgium)

ROR

<https://ror.org/04f919z92>

Funder(s)

Funder type

Industry

Funder Name

Omega Pharma N.V. (Belgium)

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	01/01/2010		Yes	No