ISRCTN96469780 https://doi.org/10.1186/ISRCTN96469780

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Ian Burgess

Contact details
Medical Entomology Centre
Insect Research & Development Limited
Cambridge House
Barrington Road
Shepreth
Royston
United Kingdom
SG8 6QZ
+44 1763 263011
ian@insectresearch.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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)

Study design
Randomised, controlled, assessor blind, parallel group study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
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 measure
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

Secondary outcome measures
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

Overall study start date
23/03/2008

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

Age group
Not Specified

Sex
Both

Target number of participants
100

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
England

United Kingdom

Study participating centre
Medical Entomology Centre
Royston
United Kingdom
SG8 6QZ

Sponsor information

Organisation

Omega Pharma N.V. (Belgium)

Sponsor details
Venecoweg 26
Nazareth
Belgium
B-9810

Sponsor type
Industry

Website
http://www.omega-pharma.be

ROR
https://ror.org/04f919z92

Funder(s)

Funder type
Industry

Funder Name
Omega Pharma N.V. (Belgium)

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	01/01/2010		Yes	No