

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

<b>Submission date</b> 07/04/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 29/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/09/2017	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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 Lynclear® spray away (ParaNix® spray) compared with Infectopedicul® permethrin 0.5% lotion in the treatment of head lice

### Study objectives

To investigate superiority of Lynclear® 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 Lynclear® 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 Lynclear® 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?
<a href="#">Results article</a>	results	01/01/2010		Yes	No