# Comparison of phenothrin mousse, phenothrin lotion and wet-combing for head lice

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
04/07/2013		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
30/07/2013		[X] Results		
Last Edited	Condition category	Individual participant data		
26/08/2016	Infections and Infestations			

## Plain English summary of protocol

Background and study aims

Some head louse treatments are not effective because they are difficult to use. This trial looked at a mousse containing phenothrin, an insecticide that is used in other products for killing head lice. We think that the mousse is easier to use. The mousse was compared with another product (phenothrin lotion) used to get rid of lice and the wet-combing method (also known as "Bug Busting").

## Who can participate?

Anyone over 4 years of age who had head lice could take part.

#### What does the study involve?

The participants were randomly allocated to receive one of the three treatment methods: mousse, lotion or wet-combing. The mousse and lotion treatments were applied on the first day with four follow-ups over 2 weeks to see how well they worked. The wet-combing treatment was given on four occasions 4 days apart, with follow-up checks on the 14th, 21st, and 28th days.

What are the possible benefits and risks of participating?

The possible benefit of the trial was that patients could get rid of their head lice without charge. The possible risks of the trial were discomfort or irritation where the treatment was applied either during or after the treatment.

Where is the study run from?

Medical Entomology Centre, Insect Research & Development Limited (UK)

When is the study starting and how long is it expected to run for? June 1997 to March 1998

Who is funding the study? Seton Healthcare Group Plc (UK) Who is the main contact? Mr Ian Burgess ian@insectresearch.com

## **Contact information**

## Type(s)

Scientific

#### Contact name

Mr Ian Burgess

#### Contact details

Medical Entomology Centre
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## Additional identifiers

#### Protocol serial number

CT 100

## Study information

#### Scientific Title

A randomised controlled assessor-blind parallel group clinical trial to assess the efficacy, safety and acceptability of phenothrin mousse, phenothrin lotion and wet-comb technique in the eradication of head lice

## Study objectives

To compare the efficacy, safety, and acceptability of phenothrin lotion and the wet-comb technique in the eradication of head lice, and to assess whether phenothrin lotion and phenothrin mousse are equivalent in terms of efficacy, safety, and acceptability.

## Ethics approval required

Old ethics approval format

### Ethics approval(s)

North Bedfordshire District Ethics Committee and South Bedfordshire Research Ethics Committee

## Study design

Randomised comparator-controlled assessor-blind single-centre study

### Primary study design

Interventional

## Study type(s)

Treatment

### Health condition(s) or problem(s) studied

Head louse (Pediculus capitis) infestation

#### Interventions

- 1. d-phenothrin 0.5% mousse in an alcohol/water emulsifying wax base plus butane propellant supplied in 50mL pressurised containers, used once by application to dry hair for 30 minutes followed by shampoo washing.
- 2. d-phenothrin 0.2% lotion in an alcohol/water base supplied in 50mL bottles, used once by application to dry hair for 2 hours followed by shampoo washing.
- 3. Wet-combing using combs from the "Bug Buster" pack to comb out lice from shampooed and heavily conditioned hair, supplied from 1 bottle of non-medicated frequent use shampoo and 4 60mL bottles of non-medicated conditioner.

#### Intervention Type

Drug

#### **Phase**

Not Applicable

## Drug/device/biological/vaccine name(s)

Phenothrin

### Primary outcome(s)

- 1. The between-treatment comparison of the number of participants with evidence of active head lice infestation 14 days after treatment.
- 2. In the case of the two insecticide-based treatments this meant that no lice should be found during the follow up assessments up to the 14th day after application of the product.
- 3. In the case of wet-combing this referred to the assessment on the 14th day after initiation of treatment and for 14 days thereafter, i.e. to the 28th day.

## Key secondary outcome(s))

Comparison between treatments with respect to occurrence of untoward effects, whether or not they are thought to be related to the study treatment.

## Completion date

02/03/1998

# **Eligibility**

### Key inclusion criteria

- 1. Males and females over the age of 4 who are suffering from head lice
- 2. People who give written informed consent or, if the person is under 18 years of age, whose guardians give written informed consent to participate in the study
- 3. People who are available for visits from the research investigators over the following 28 days

4. People who have an adult/guardian who is able to treat or comb the hair (depending on the allocated treatment group)

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Mixed

#### Sex

All

#### Key exclusion criteria

- 1. People with a known sensitivity to pyrethroid insecticides and/or chrysanthemums
- 2. People who have been treated with other head lice products within the last 4 weeks
- 3. People who have any persistent skin disorder of the scalp (i.e. eczema, chronic dermatitis, psoriasis)
- 4. People receiving treatment for asthma
- 5. People who have bleached hair, or hair which has been colour treated or permed within the last 4 weeks
- 6. Pregnant or nursing mothers
- 7. People who have participated in another clinical trial within 1 month prior to entry to this study
- 8. People who have already participated in this clinical trial
- 9. People who have been treated with antibiotics within the last 4 weeks

#### Date of first enrolment

14/06/1997

#### Date of final enrolment

02/03/1998

## Locations

#### Countries of recruitment

United Kingdom

England

Study participating centre
Insect Research & Development Limited

Cambridge United Kingdom CB25 9AU

# Sponsor information

## Organisation

Seton Healthcare Group Plc (UK)

#### **ROR**

https://ror.org/01g87hr29

# Funder(s)

## Funder type

Industry

#### Funder Name

Seton Healthcare Group Plc (UK)

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	<b>Details</b> results	Date created Date added Peer reviewed? Patient-facing?		
Results article		10/07/2014	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes