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

Submission date	Recruitment status	[_] Prospectively registered
04/07/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/07/2013	Completed	[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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
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 measure
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.

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

Overall study start date
14/06/1997

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

Age group
Mixed

Sex
Both

Target number of participants
266 participants divided between treatments in the ratio 104 : 104 : 58

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
England

United Kingdom

Study participating centre
Insect Research & Development Limited
Cambridge
United Kingdom
CB25 9AU

Sponsor information

Organisation
Seton Healthcare Group Plc (UK)

Sponsor details
Tubiton House
Medlock Street
Oldham
United Kingdom
OL1 3HS

Sponsor type
Industry

ROR
https://ror.org/01g87hr29

Funder(s)

Funder type
Industry

Funder Name
Seton Healthcare Group Plc (UK)

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	10/07/2014		Yes	No