ISRCTN91870666 https://doi.org/10.1186/ISRCTN91870666

A multicentre phase III trial of 1,2-octanediol at 5% (w/v) (KindaPed™) compared with malathion 0.5% (w/v) (Derbac-M Liquid®) in the treatment of head lice

Submission date	Recruitment status	[X] Prospectively registered
09/05/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/05/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/08/2012	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CT:EP02

Study information

Scientific Title

Study objectives
To compare the efficacy of each of two different application regimens (two-hour and eight-hour) of KindaPed™ with the standard regimen of Derbac-M Liquid® in eliminating infestation (achieving cure or re-infestation) following two treatment applications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Trent Research Ethics Committee on the 13th July 2007 (ref: 07/MRE04/39).

Study design
Phase III, randomised, assessor-blind, multicentre, parallel group trial

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
Treatment of head louse infection

Interventions
The participants hair will be combed with a fine toothed comb at the start of the study and on a further five occasions in order to assess the level of head lice infection. The study treatment will be applied on the treatment days (two days one week apart).

Intervention (1,2-octanediol at 5% [w/v] [KindaPed™]):
Dosage will be one bottle (100 ml) applied for either two hours or for eight hours to dry hair. Enough product will be used to soak the hair. A second bottle may be used if the hair is long and

/or thick. The hair will be left to dry naturally and washed the following morning with normal shampoo and dried in the normal fashion. The product is applied on Day 0 of the trial and again on Day 7 (± 1 day). The subjects will be followed up until their final visit on Day 14. Any adverse events will be followed until resolution or stabilisation.

Comparator (malathion 0.5% [w/v] [Derbac-M Liquid®]):
Dosage will be one bottle (200 ml) applied for eight hours to dry hair. Enough product will be used to soak the hair. The hair will be left to dry naturally and washed the following morning with normal shampoo and dried in the normal fashion. The product is applied on Day 0 of the trial and again on Day 7 (± 1 day). The subjects will be followed up until their final visit on Day 14. Any adverse events will be followed until resolution or stabilisation.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
1,2-octanediol at 5% (w/v) (KindaPed™), malathion 0.5% (w/v) (Derbac-M Liquid®)

Primary outcome measure
The primary endpoint is the proportion of subjects satisfying the criteria for cure or re-infestation as defined by the treatment outcome algorithm. These subjects will all have been cured of the infestation evident at Day 0.

Secondary outcome measures
Secondary measures will be:
1. The proportion of subjects satisfying the criteria for cure based only on the assessments at Days 2and 6 following the first treatment application
2. The proportion of subjects satisfying the criteria for killing lice following two treatment applications
3. The proportion of subjects satisfying the criteria for killing eggs following two treatment applications
4. The safety of the study products, as determined by the occurrence of adverse events
5. Ease of application of the study products as assessed by an investigator questionnaire
6. Subject assessment of acceptability

Overall study start date
07/09/2007

Completion date
28/02/2008

Eligibility

Key inclusion criteria
1. Subjects aged four and over
2. Subjects who upon examination are confirmed to have live head lice
3. Subjects who have given written informed consent, or, if the subject is less than 16 years of

age, whose parent/guardian has given written informed consent to participate in the study
4. Subjects who will be available for home visits from research staff over the 15 days of the study

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
420

Key exclusion criteria
1. Subjects with a known sensitivity to any of the ingredients in the products
2. Subjects 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)
3. Subjects currently on prescribed medication for the prophylaxis or treatment of asthma (currently will be interpreted as meaning that the subject has used asthma medication within the previous four months)
4. Subjects who have been treated with other head lice products within the last two weeks. There must have been a 14-day gap since treatment for head lice was last used before the subject can be accepted into this trial
5. Subjects who have bleached hair, or hair that has been colour treated or permanently waved within the last four weeks (wash in/wash out colours are acceptable)
6. Subjects who have been treated with the antibiotics Co-Trimoxazole, Septrin or Trimethoprim within the previous four weeks, or who are currently taking such a course
7. Pregnant or nursing mothers
8. Subjects who have participated in another clinical trial within one month prior to entry to this study
9. Subjects who have already participated in this clinical study or any clinical study of KindaPed™

Date of first enrolment
07/09/2007

Date of final enrolment
28/02/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Medical Entomology Centre
Royston
United Kingdom
SG8 6QZ

Sponsor information

Organisation
EctoPharma Ltd (UK)

Sponsor details
54 Queen Street
Edinburgh
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EH2 3NS

Sponsor type
Industry

Website
http://www.ectopharma.com

Funder(s)

Funder type
Industry

Funder Name
EctoPharma Ltd (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	01/07/2012		Yes	No