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A phase IIa clinical trial to demonstrate proof of concept of an experimental pediculicide lotion for the treatment of head lice

Submission date 02/06/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/07/2006	**Overall study status** Completed	
Last Edited 13/08/2012	**Condition category** 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:EP01

Study information

Scientific Title

Acronym
KindaPed

Study objectives
The primary aims of this trial are to assess the efficacy and safety of KindaPed™ to eradicate head lice infection.
The secondary aims are to assess the ease of application of the product and to show the amount of lotion used for each participant and thus enable the sponsor to establish the average amount of product required for treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval by Hertfordshire Research Ethics Committee 2 (REC 2) on 25/05/2006, reference number is 06/Q0204/15

Study design
Open label, non-controlled proof of concept study

Primary study design
Interventional

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Head lice infestation

Interventions
The product will be applied directly to dry hair. Sufficient product will be applied to thoroughly moisten the hair and scalp. The product will be left in place overnight before being shampooed and rinsed off with water the next morning. The product will be reapplied at day 7(+/-1 day).

Intervention Type
Drug

Phase
Phase II

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

Primary outcome measure
1. To assess the efficacy of KindaPed™ to cure head lice infection
2. To assess the efficacy of KindaPed™ to kill head lice
3. To evaluate the efficacy of KindaPed™ to kill louse eggs
4. To monitor the safety and acceptability of KindaPed™ in clinical use

Secondary outcome measures
1. To assess the ease of application of KindaPed™
2. To assess the total treatment dose for each participant, and to calculate an average dose level for this product

Overall study start date
08/06/2006

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Patients aged four and over
2. Patients who upon examination, are confirmed to have live head lice
3. Patients who give their written informed consent, or if the patient is less than 16 years of age, whose parent/guardian gives written informed consent to participate in the study
4. Patients who will be available for home visits from Medical Entomology Centre (MEC) study team members over the 15 days of the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria

1. Patients with a known sensitivity to any of the ingredients in the product
2. Patients 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. Patients known to suffer from asthma
4. Patients who have been treated with other head lice products within the last two weeks. There must be a 14-day gap since treatment for head lice was last used before the patient can be accepted on to this trial.
5. Patients 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. Patients who have been treated with the antibiotics co-trimoxazole, septrin or trimethoprim within the last four weeks, or who are currently taking such a course
7. Pregnant or nursing mothers
8. Patients who have participated in another clinical study within one month before entry to this study
9. Patients who have already participated in this clinical study

Date of first enrolment
08/06/2006

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
EctoPharma Limited (UK)

Sponsor details
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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
EctoPharma Limited

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	01/09/2012		Yes	No