

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

Registration date
20/07/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
13/08/2012

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Open label, non-controlled proof of concept study

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

The Medical Entomology Centre

Royston

United Kingdom

SG8 6QZ

Sponsor information

Organisation

EctoPharma Limited (UK)

Funder(s)

Funder type

Industry

Funder Name

EctoPharma Limited

Results and Publications

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