

Kindaped™ lotion for treatment of head lice

Submission date 27/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/10/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/08/2012	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CTMK12

Study information

Scientific Title

A randomised, assessor blinded, clinical trial to confirm the efficacy of a CE marked class I medical device formulation in the treatment of head lice

Study objectives

A randomised, assessor blind clinical investigation designed to confirm efficacy in use and obtain further information about routine usage of two variants of the same CE marked class I medical device product based on 1,2-octanediol in the control and elimination of head louse infestation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Leeds (West) Research Ethics Committee approved (provisionally) on the 20th September 2010 (ref: 10/H1307/106)

Study design

Two-centre randomised three-arm comparative 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 infestation

Interventions

Group A: KindaPed AF (5% 1,2-octanediol alcohol free lotion), applied for 2 hours (maximum 2.5 hours) before washing off using shampoo, with a repeat treatment one week later.

Group B: KindaPed AF (5% 1,2-octanediol alcohol free lotion), applied for 8 hours (minimum) or overnight before washing off using shampoo, with a repeat treatment one week later.

Group C: KindaPed lotion (5% 1,2-octanediol lotion with 20% alcohol), applied for 2 hours (maximum 2.5 hours) before washing off using shampoo, with a repeat treatment one week later.

Intervention Type

Other

Phase

Phase II/III

Primary outcome measure

Cure of infestation, defined as no evidence of head lice, assessed between completion of the second application of treatment on day 7 and day 14 (the first treatment being applied on day 0).

Secondary outcome measures

1. Prevention of louse egg hatching (ovicidal action), defined as no 1st and 2nd stage nymphs found at assessments during the week following the first treatment or after the second application of treatment
2. Safety of the product monitored by observation for adverse events on days 0, 1, 6, 7, 9, and 14 of the study
3. Ease of use by investigators, assessed by a questionnaire on the day of the first treatment
4. Participant acceptability, assessed by a questionnaire at the final assessment on day 14

Overall study start date

10/10/2010

Completion date

31/12/2010

Eligibility**Key inclusion criteria**

1. Both males and females, aged 6 months and over with no upper age limit
2. People who upon examination, are confirmed to have live head lice
3. People who give written informed consent, or if the participant is under 16 years of age whose parent/guardian gives written informed consent to participate in the study
4. People who will be available for follow-up visits by study team members over the 14 days following first treatment

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Sex

Both

Target number of participants

120 divided into three groups of 40

Key exclusion criteria

1. People with a known sensitivity to any of the ingredients in KindaPed AF (5% 1,2-octanediol alcohol free lotion) or in KindaPed lotion (5% 1,2-octanediol lotion with 20% alcohol)
2. People with a secondary bacterial infection of the scalp (e.g. impetigo) or who have an active long-term scalp condition (e.g. psoriasis of the scalp)
3. People who have been treated with other head lice products within the previous two weeks
4. People who have bleached hair, or hair that has been permanently waved within the previous four weeks
5. People who have been treated with the antibiotics co-trimoxazole or trimethoprim within the previous four weeks, or who are currently taking such a course
6. Pregnant or nursing mothers
7. People who have participated in another clinical study within 1 month before entry to this study
8. People who have already participated in this clinical study

Date of first enrolment

10/10/2010

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Medical Entomology Centre

Cambridge

United Kingdom

CB25 9AU

Sponsor information

Organisation

Thornton & Ross Ltd (UK)

Sponsor details

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Sponsor type
Industry

Website
<http://www.thorntonross.com>

ROR
<https://ror.org/00frd0c49>

Funder(s)

Funder type
Industry

Funder Name
Thornton & Ross 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	01/04/2012		Yes	No