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Kindaped™ lotion for treatment of head lice

Submission date	Recruitment status	[_] Prospectively registered
27/09/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/10/2010	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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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).

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Sex
All

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
United Kingdom

England

Study participating centre
Medical Entomology Centre
Cambridge
United Kingdom
CB25 9AU

Sponsor information

Organisation
Thornton & Ross Ltd (UK)

ROR
https://ror.org/00frd0c49

Funder(s)

Funder type
Industry

Funder Name
Thornton & Ross Ltd (UK)

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	01/04/2012		Yes	No