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Comparing mosquito® LäuseShampoo with Infectopedicul® lotion

Submission date	Recruitment status	[X] Prospectively registered
23/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
05/02/2014	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Some head louse treatments are not effective because they are difficult to use or are affected by insecticide resistance. This trial looked at a shampoo containing soya oil as an active material to coat the lice (mosquito®LäuseShampoo) and compared it with an insecticide-based product containing 0.5% permethrin used extensively in Germany (InfectoPedicul® lotion).

Who can participate?
Anyone over 2 years of age who had head lice could take part.

What does the study involve?
The participants were randomly allocated to receive one of the two treatment methods: shampoo or lotion. Both treatments were applied on the first day, with repeat treatment after 9 days, and there were four follow-ups over 2 weeks to see how well they worked.

What are the possible benefits and risks of participating?
The possible benefit of the trial was that patients could get rid of their head lice without charge. The possible risks of the trial were discomfort or irritation where the treatment was applied either during or after the treatment.

Where is the study run from?
Medical Entomology Centre, Insect Research & Development Limited, UK.

When is the study starting and how long is it expected to run for?
The study started in June 2010 and ran until December 2010.

Who is funding the study?
Wepa Apothekenbedarf GmbH & Co KG.

Who is the main contact?
Mr Ian Burgess
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
2010-019804-21

Protocol serial number
CTWE01

Study information

Scientific Title
A randomised, controlled, assessor-blind, clinical investigation of the activity of mosquito® LäuseShampoo compared with Infectopedicul® permethrin 0.5% lotion in the treatment of head lice

Study objectives
To investigate:
1. Non-inferiority of mosquito® LäuseShampoo to Infectopedicul® in the eradication of head louse infestation
2. If a sufficient difference in efficacy is identified to detect superiority of mosquito® LäuseShampoo compared with Infectopedicul®
3. To compare the products for safety, ease of application and participant acceptability

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 05/02/2014: Oxfordshire REC Committee A, ref: 10/H0604/30

Study design
Randomised controlled assessor blind parallel group study

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Participants will be randomly divided into two equal groups.

Half the participants (48) will receive mosquito® LäuseShampoo (modified coconut oil and soya oil based shampoo): the product is first used like an ordinary shampoo and partially towel dried. The product will be applied directly to the damp hair. Sufficient product will be applied to the hair and scalp that when thoroughly massaged in produces a homogenous and stable foam, which covers all the hair and the scalp. If no such foam is built, more product has to be applied. The foamed product will be left in place for 30 minutes (a shower cap will be used to secure the foam) before being rinsed off with warm water and towel dried. The product is then reapplied to produce a stable foam and left in place for a further 30 minutes (maximum dose 100 ml per treatment application). The product will be reapplied at Day 9.

The other half (48) will receive Infectopedicul® 0.5% permethrin alcoholic lotion: The product will be applied directly to washed and towel dried hair. Sufficient product will be applied to saturate the hair and scalp (maximum dose 100 ml per application). The product will be left in place for 30 minutes before being rinsed off with warm water. The product will be reapplied at Day 9.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
mosquito® LäuseShampoo, Infectopedicul® lotion

Primary outcome(s)
To investigate the non-inferiority of mosquito® LäuseShampoo in comparison with Infectopedicul® lotion in the eradication of head louse infestation, defined as no evidence of head lice, assessed between completion of the second application of treatment on day 9 and day 14 (the first treatment being applied on day 0).

Key secondary outcome(s))
1. If there is sufficient margin in efficacy, to detect superiority of efficacy of mosquito® LäuseShampoo over Infectopedicul® lotion in the eradication of head louse infestation
2. To compare mosquito® LäuseShampoo with Infectopedicul® lotion with regard to the following factors:

2.1. Safety of the products monitored by observation for adverse events on days 0, 2, 9, 11, and 14 of the study
2.2. Ease of use by investigators, assessed by a questionnaire on the day of the first treatment
2.3. Participant acceptability, assessed by a questionnaire at the assessment on day 2

Completion date
31/08/2010

Eligibility

Key inclusion criteria
1. Both males and females aged 2 years and over with no upper age limit
2. Participants who upon examination, are confirmed to have at least five live head lice
3. Participants who give written informed consent, or if the participant is below 16 years of age whose parent/guardian gives written informed consent to participate in the study
4. Participants who will be available for home visits by study team members over the 14 days following first treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. People younger than 2 years
2. People with a known sensitivity to pyrethroid insecticides like permethrin, chrysanthemums, nuts, soya, or any of the ingredients in mosquito® LäuseShampoo or Infectopedicul® lotion
3. People with asthma or a similar respiratory condition
4. People 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)
5. People who have been treated with other head lice products within the previous two weeks
6. People who have been treated with the antibiotics co-trimoxazole, trimethoprim or any other medical treatment which could interfere with the study treatment within the previous four weeks, or who are currently taking such a course
7. People who have bleached, permanently coloured, or permanent waved their hair within the previous four weeks
8. People or parents/guardians not giving written consent or withdrawal of the written consent
9. Pregnant or nursing mothers. Any potential participant in menses should confirm that they are not or not likely to be pregnant or are taking an appropriate form of contraception. In case of doubt a urine pregnancy test may be performed prior to entry.
10. People who have participated in another clinical study within 1 month before entry to this study
11. People who have already participated in this clinical study

Date of first enrolment
01/05/2010

Date of final enrolment
31/08/2010

Locations

Countries of recruitment
United Kingdom

England

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

Sponsor information

Organisation
Wepa Apothekenbedarf GmbH & Co KG (Germany)

ROR
https://ror.org/01y84kk86

Funder(s)

Funder type
Government

Funder Name
Wepa Apothekenbedarf GmbH & Co KG (Germany)

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	01/04/2011		Yes	No
HRA research summary			28/06/2023	No	No