# Comparing mosquito® LäuseShampoo with Infectopedicul® lotion

Submission date	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
23/03/2010		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
08/04/2010		[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 ian@insectresearch.com

## **Contact information**

#### Type(s)

Scientific

#### Contact name

Mr Ian Burgess

#### Contact details

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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/quardian 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes