ISRCTN50658447 https://doi.org/10.1186/ISRCTN50658447

Vamousse® shampoo to prevent the spread of headlice to other people living in the same household

Submission date
25/02/2022

Recruitment status
No longer recruiting

Registration date
25/02/2022

Overall study status
Completed

Last Edited
20/05/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Many people have expressed a wish for a product that protects against head louse infestation spreading in a family. Specially designed products used regularly have been shown to help prevent the spread of lice in families. The new product that we are testing is a shampoo, so it should be easier to use thoroughly than some other types of product. We think this will dissolve the protective waxy coat of the lice and make them dry out, which will stop any lice that get onto you from establishing an infestation. We are going to compare the effect of the product with a similar shampoo but with no active ingredients (placebo) so we would expect to find a difference in the number of infestations in other household members if you are using the active shampoo rather than the placebo.

Who can participate?
Families with more than one child attending school. One of these must have a current case of head lice.

What does the study involve?
Taking part in the study will last about 14 days altogether. The child with head lice will first be treated to eliminate the lice using Vamousse Treatment Mousse. We shall check this has worked after 3 days and if there are still any lice, we shall give a second treatment. At a third check on Day 6 we could also give a third treatment if necessary.
After the first treatment everyone taking part will be able to use the Vamousse Lice Defence Shampoo or placebo shampoo every day. There will be enough shampoo to last for 14 days. If you run out, we can supply more. At the end of the 14 days we shall check everyone in the house to see if anyone has caught lice. They will be then offered treatment to eliminate the infestation. All the work will be done in your home. We shall visit at a time that is convenient for you and your family, to check how you got along. It should not interfere with school, work, or social activities. The first visit takes longest, about 45 minutes. Other visits take no more than a few minutes.
At the first visit everyone in the house who wants to take part will be asked to sign a consent form, or for children an assent form.

We shall ask everyone who joins some questions about their health and any medicines they are taking at the time of joining. During the study we shall also ask if they have had any accidents, felt unwell, or started or stopped any medicines. If we think there is any reason it would be better for you to withdraw from the study at any time we shall tell you and you will not need to take part in any more of the study.
Half the people joining the study will be treated with Vamousse Lice Defence Shampoo. The other half will be treated with the placebo shampoo. The treatments will be allocated on a random basis. The two treatments are similar in appearance and smell so nobody, even the investigators, will know which treatment you are receiving.
Both shampoos are applied to wet hair in just the same way as a normal shampoo. The foam is left on the hair for at least 3 minutes but not more than 5 minutes and then rinsed out. Everybody will be asked to use the product daily but at least every other day if this is not possible.
On the first occasion, a member of the study team will show you how to apply the treatment, but after that it should be applied by an adult in the household.
A different member of the team will visit to do the final check-up. We shall give you an diary card to record when you used the shampoo, any accidents or illnesses, and to remind you which day we are visiting, but we shall also send you an SMS (text message) or phone call the day before to check that it's still convenient to visit.
If anyone in the house catches lice during the study, we shall be able to provide them with treatment and that will be the end of their taking part. At the end of the study everyone who needs it will be given further treatment to make sure there are no lice.
Please do not use any other head louse treatments, or check or comb for head lice, as we will do it all for you. We also request you not to use other hair care products, such as conditioners or hair gels and sprays for the duration of the study. If you use any other products or treatment methods you will be withdrawn from the study.

What are the possible benefits and risks of participating?
You will not be paid for taking part in the study but we shall make sure that any head lice you have at the beginning, or catch during the study, will be cleared.
If the product accidentally gets into your eyes it may irritate like any other shampoo. Just rinse with water.
It is important that you tell us if you feel ill in any way while you are taking part in the study. Please do this even if you think it has nothing to do with head lice or the treatment.
In the unlikely event that anyone experiences an allergic reaction to any of the treatments they should contact us immediately on one of the numbers given at the end of this information so that we can get you the best advice for dealing with it. This may be contacting a pharmacist, your GP, or NHS 111.

Where is the study run from?
The study is run from the Medical Entomology Centre in Cambridge (UK), but all study visits will take place in the participants' homes.

When is the study starting and how long is it expected to run for?
October 2019 to April 2023

Who is funding the study?
Alliance Pharmaceuticals Limited are the company supplying Vamousse products in the UK. They have asked the Medical Entomology Centre to run the study for them because we specialise in working with lice. We will be paid for getting rid of any lice you may have, showing you how to use the product, and checking how it works.

Who is the main contact?
Ian Burgess
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
286424

Protocol serial number
VAM2301(CTAP01)

Study information

Scientific Title
Prevention of infestation with Pediculus humanus capitis in the family group using a pediculicidal shampoo: A prospective, randomised controlled study.

Study objectives
Vamousse® shampoo is superior to a control shampoo in reducing the spread of headlice between individuals in a household.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 21/09/2020, London - Stanmore REC (Health Research Authority, Skipton House, 80 London Rd., London, SE1 8RH, UK; +44 (0)207 972 2561; stanmore.rec@hra.nhs.uk), ref: 20/LO/1022

Primary study design
Interventional

Study design
Single center prospective interventional double-blind randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Pediculus capitis (headlice) infestation within a household group living under the same roof.

Interventions
Following confirmation of index case(s) within a household group, the index case(s) will be treated with a headlice treatment with known efficacy (Vamousse® Mousse). Households will then be randomised to receive one of two follow-up regimes, which will be taken by all members of the household:
1. Daily hair washing (leave in for 3 minutes) with Vamousse® shampoo for 14 days.
2. Daily hair washing with a non-medicated, commercially-available shampoo matched for fragrance & consistency to the investigational product, also for 14 days.
Randomisation is by sealed envelopes, with an eight number block sequence generated on randomisation.com. Index cases will be inspected on days 3 & 6 for the presence of live lice or nymphs and will receive an additional treatment with Vamousse® mousse if any are found.

Intervention Type
Supplement

Primary outcome(s)
The proportion of subjects in each household with live lice or nymphs at day 14 measured by thorough detection combing by the investigator team

Key secondary outcome(s)
Cosmetic acceptability of the shampoo, collected by participant diary entries throughout the study period

Completion date
30/04/2023

Eligibility

Key inclusion criteria
1. Males and females, minimum age 4 years, with no upper age limit who are family members of an eligible index case (as defined below).
2. People who upon examination, are confirmed to have an active infestation with head lice, as shown by presence of at least one live louse on Day 0 are eligible as index cases. For the

purposes of randomisation, only the first presenting case in a household shall be considered a Primary index case.
3. People who give written informed consent or, if the prospective 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 home visits by MEC study team members over the 15 days of the study.
5. Primary Index cases should preferably be children between the ages of 5 & 11 years but not adults, although adults may be secondary index cases, and must have at least one sibling of similar age, with at least one responsible adult living under the same roof.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. Anyone with a known sensitivity to any of the ingredients in Vamousse Lice Defence Shampoo, or The Control Shampoo.
2. Anyone with a secondary bacterial infection of the scalp (e.g. impetigo) or who has a long-term scalp condition (e.g. psoriasis of the scalp).
3. Anyone who has used treatment for head lice infestation within the previous 7 days.
4. Anyone who has been treated using a trimethoprim-based antibiotic product during the past 4 weeks or who is currently under such treatment.
5. Pregnant or breast-feeding mothers.
6. Anyone who has participated in another clinical study within 1 month before entry to this study.
7. Anyone who has already participated in this clinical study.

Date of first enrolment
15/03/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Medical Entomology Centre
Insect Research and Development Ltd
6 Quy Court
Colliers Lane
Stow-cum-Quy
Cambridge
United Kingdom
CB25 9AU

Sponsor information

Organisation
Alliance Pharmaceuticals (United Kingdom)

ROR
https://ror.org/001zd1d95

Funder(s)

Funder type
Industry

Funder Name
Alliance Pharmaceuticals Ltd.

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results			20/05/2024	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version 1.2	04/11/2021	25/02/2022	No	Yes
Protocol file	version 2.1	03/11/2021	25/02/2022	No	No

Statistical Analysis Plan	version 1.0	20/05/2021	25/02/2022	No	No