

# **Can we prevent head lice spreading in families?**

## **Information for Families**

# Can we prevent head lice spreading in families?

## **Participant Information Booklet**

**Full Title:** Prevention of infestation with *Pediculus humanus capitis* in the family group using a pediculicidal shampoo: A prospective, randomised controlled study. (**Protocol VAM2301, Version: 2.1, 3<sup>rd</sup> November 2021**)

We are inviting you to take part in a research study. This booklet explains why the research is being done and what it will involve. Please take time to read the following information carefully. It is important you understand what is involved. It will help you decide if you want to take part. You may wish to discuss it with your family, friends, or your GP. Please ask questions if anything is unclear or if you would like more information. Please take time to decide if you want to take part.

The Medical Entomology Centre has been asked to carry out this study by the makers of the product (Alliance Pharmaceuticals Limited).

We are happy to talk to you over the phone about this study. But you need to read this information and need to think about whether you should join the study. This booklet gives important information and the answers to the most frequently asked questions.

### **What is the purpose of this study?**

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 is organising and 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.

### **Can anyone take part?**

We would like to recruit 84 volunteer families, with more than one child attending school. One of these must have a current case of head lice. However, there are some people who cannot take part.

You won't be able to join if you:

- are pregnant, trying to become pregnant, or are breast-feeding;
- have a known sensitivity to any ingredients in Vamousse Treatment Mousse, the Vamousse Lice Defence Shampoo, or the placebo shampoo;
- have a bacterial infection of the scalp, for example impetigo, or if you have a condition like psoriasis on the scalp;
- have taken a trimethoprim-based antibiotic in the last 4 weeks or been treated for head lice in the last 7 days;
- have taken part in another clinical trial within the last 4 weeks;\*
- have previously taken part in this study.

\*In this case you will be able to enter the study after a short delay period.

### **Do I have to take part?**

Joining the study is voluntary. You don't have to join and you can leave anytime without giving a reason. If you do decide to leave, and we have done something wrong, please tell us why so we can try to put things right. If you do decide to leave, you can treat your head lice in the usual way.

### **What will happen if I take part?**

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.

### **Do I have to do anything?**

During the course of the study an adult in the household will apply the shampoo treatment daily or at least every other day.

There is no need to comb through the hair looking for head lice because we will do all the necessary checking for lice using our plastic louse comb. You may not use any combing treatment method either.

Please make sure you are able to keep the appointment for the check-up. If there is a problem with an appointment let us know and we will re-arrange the time.

**Are there any risks or side effects if I take part?**

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.

**Will there be any benefits from me taking part?**

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.

**What if relevant new information becomes available?**

If we receive any new information on the product, we will discuss it with you. You can then decide if you wish to continue in the study. If the sponsor decides to stop the research we shall explain the reasons for this.

**Will you tell my doctor that I am taking part?**

We will ask you if we can tell your General Practitioner (GP) that you are taking part. Although we would prefer to do this, you may still join the study without giving this permission.

**Who will have access to my personal details?**

The Medical Entomology Centre takes protection of your personal data very seriously. Through its parent company (Insect Research & Development Limited) it is registered with the office of the Information Commissioner and we will always respect your privacy and will only use your information for specified and lawful purposes as provided for under the General Data Protection Regulation (GDPR). We will use and handle your information responsibly and will take all appropriate organisational and technical measures to safeguard your information from accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access.

A copy of our Privacy Notice will be given to you at the time you join the study.

The only people who will know your name and address are the people who come to see you. By law, we must keep these details safe and secure. The only exception to this is if the researcher observes any abuse or neglect of children or vulnerable adults, which they have a duty to report.

When you join the study, you will be given a number. **You will only be identified by this number to the company that has asked us to conduct this study**, and to their partner companies, and regulatory authorities.

### **What if there is a problem?**

If you are unhappy with any aspect of this study, you should ask to speak to the researchers. They will do their best to answer your questions or solve any problems. You can make contact by calling 08454 300 300. If you are still unhappy and wish to complain formally, you can write to the Medical Entomology Centre at the address shown on this booklet.

### **Will I have to sign anything?**

Adults and parents/carers who want a member of the family to join the study will be asked to sign a consent form. This explains that you, or a child in your care, have agreed to take part in the study as set out in this Information booklet. Children under 16 have a special assent form to sign. You will be given a copy of any forms signed by you for you to keep with this booklet.

As part of this consent you will be asked to give permission for the data collected to be used by Alliance Pharmaceuticals Limited, their partner companies, or by regulatory authorities, and NHS or independent auditors (for monitoring the quality of the research). All will have a duty of confidentiality to you as a participant and nothing that could reveal your identity will be disclosed outside the research site.

### **Can I leave the study if I want to?**

You can choose to leave the study at any time. If you decide to leave the study we shall ask if any data already collected can be used as part of the clinical study information. This will be available to Alliance Pharmaceuticals Limited and their partner companies or the regulatory authorities.

If you decide to leave the study you may be able to get a prescription from your GP or buy any further head louse treatments required over the counter from your pharmacy or from a supermarket.

### **What will happen to the results from this study?**

Medical Entomology Centre will store the personal details and data of all participants in this study securely for a period of 25 years.

Only anonymous data from the study (study number) will be sent to the sponsor, Alliance Pharmaceuticals Limited.

The results of the study may eventually be published in a scientific journal. If you wish to know which one and when, please tell a member of the investigation team and we shall let you know at the time.

### **Who has given permission for this study to take place?**

Permission for this study to take place has been granted by London-Stanmore Research Ethics Committee

### **Contact for further information:**

A copy of this information is available at [www.insectresearch.com](http://www.insectresearch.com). If you would like to take part in this study please call [Elizabeth Brunton](tel:01223813696) or another member of the study team on [01223 813696](tel:01223813696) or [08454 300 300](tel:08454300300) or by email at [info@insectresearch.com](mailto:info@insectresearch.com). They will make arrangements for a team member to come to your home to see if you can join the study. We will also be able to answer any other questions you may have.

If you phone and no one is available to talk to you, please leave your name and telephone number and someone will call you back as soon as they can.



During your time on the study there is a [24-hour emergency telephone number](#) in case you need to talk to us: [07912 769787](#).

**In the event that you have a complaint about any aspect of the way this study has been conducted, please contact [Ian Burgess](#), on [08454 300 300](#).**

## Children's Information

Can we prevent head lice?

We want to see if we can stop head lice spreading round families. Nobody has to join the study, but we would like you to help us do that.



We have a shampoo that should kill lice if they get onto you. You use the product like a normal shampoo but leave it on for 3 minutes. Please use every day if possible. We are comparing it with a shampoo with no active ingredient. We don't know which shampoo you will get.

First, we shall visit you at home and get rid of any lice at the start. Then everyone in the house uses the test shampoo for hair washing. We will ask a grown up to put it on each time you use it. If you did have lice, we shall check it worked after 3 days and give another treatment if you need it.

We shall come to visit everyone after 2 weeks to see if the shampoo has worked. We shall comb your hair with a plastic louse comb. The visit will be made at a time to suit you.

if you catch lice at any time during the study, or if you have lice at the end, we shall give you a treatment.

If you want to know more about the treatment, or more about head lice - Please ask the team member who visits you.

If you feel ill during the study, or have an accident, please tell us about it.

If you change your mind, you can leave the study at any time.

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[alliancepharmaceuticals.com](http://alliancepharmaceuticals.com)

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