

Anti-Lice Protector

Information for Families

Anti-Lice Protector

Participant Information Booklet

Full Title: A clinical investigation of the activity of Anti-Lice Protector in the treatment of head lice (Protocol CTFT01, Version: 1.1, 13th January 2011)

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 Fulltec Anti-Lice Protector (Fulltec Ag, Zug, Switzerland).

Fulltec Anti-Lice Protector is a product to treat head lice. It has been used in Europe for several years. This clinical trial is to see how well it works using a shortest treatment time .

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?

Fulltec Anti-Lice Protector has not yet been scientifically tested in a large community. The company selling it want to know how well it works using a short treatment time . If it works well this would make it a more convenient product for most families.

Who is organising and funding the study?

Fulltec AG is the company supplying Fulltec Anti-Lice Protector. They are based in Zug, Switzerland. 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 treating and checking how it works.

Can anyone take part?

We would like to recruit 30 people over 2 years old with an active case of head lice. However, there are some people who cannot join in.

You won't be able to join if you:

- are pregnant, trying to become pregnant, or breast-feeding,
- have a known sensitivity to nuts, coconut or any of the ingredients in Fulltec Anti-Lice Protector ,
- treated your hair for head lice within the last 2 weeks*,
- have a bacterial infection of the scalp, for example impetigo, or if you have a condition like psoriasis on the scalp.
- have taken one of the antibiotics Cotrimoxazole or Trimethoprim, within the last 4 weeks*,
- have taken part in another clinical trial within the last 4 weeks*
- have previously taken part in this study.

*In these cases 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 17 days. All the work will be done in your home. We shall visit at a time that is convenient for you and your family. It should not interfere with school, work, or social activities. Members of the study team will visit you 4 times during the 17 day

study period. Each visit takes between 15 and 45 minutes for each person.

At the first visit everyone who wants to take part will be checked for head lice. We shall comb their hair with a fine-toothed plastic detection comb. It is important that we check the other members of your family too. If they have lice they can choose to join the study. If they have head lice but cannot join the study they will be offered a different treatment to prevent reinfestation.

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 we shall tell you and you will leave the study.

Everyone taking part will receive the same treatment.

Using Fulltec Anti-Lice Protector

1. Wash the hair normally with Fulltec Anti-Lice Protector
2. Towel dry the hair thoroughly until it is just damp
3. Fulltec Anti-Lice Protector is then applied to damp hair and thoroughly massaged in.
4. Leave the foam in place for 15 minutes (you can cover it with a shower cap).
5. Rinse the shampoo off with warm water
6. Towel dry the hair.

The product will be reapplied at Day 8.

A member of the study team will apply the treatment for you.

A different member of the team will do checkups twice between treatments. (2 days after the first treatment and immediately before the second treatment on Day 8). The last combing is after the second treatment on Day 17. This is to check how well the product has worked.

Please do not use any head louse treatments, or check or comb for head lice, as we will do it all for you. You can use your normal shampoo or conditioner at any time during the study period.

Do I have to do anything?

We would like you to rinse the test shampoo out of your hair at the end of the treatment time. **Please do not comb through the hair looking for head lice, as we will do that at the checkups.** We will use a fine-toothed plastic detection comb.

Please make sure you are able to keep the appointments for the checkups. 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?

Fulltec Anti-Lice Protector is a coconut based shampoo. It contains 1% fractionated coconut oil in a shampoo base. This is made from:

water,
sodium laureth sulphate,
potassium octanoate,
sodium chloride,
cocamidopropyl betaine,
cocamide DEA,
perfume,
hydrolyzed collagen,
hydrolyzed wheat protein.

Shampoos and conditioners you already use probably contain some of these things.

A small number of people may feel itching or get dry skin after treatment, mainly due to louse bites. If the product drips into your eyes it may irritate. Just rinse with water. Some people feel more itchy or irritated on their neck or scalp while the treatment is in place.

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.

Will there be any benefits from me taking part?

You will not be paid for taking part in the study but we do expect that your head lice will be cleared. If that does not happen then we will offer you a different treatment.

What if relevant new information becomes available?

If any we receive new information on this treatment, 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 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.

If something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a

legal action for compensation against Medical Entomology Centre but you may have to pay your legal costs.

The study sponsor, Fulltec AG, will provide compensation for any injury caused by taking part in this study that will be consistent with the guidelines of the Association of the British Pharmaceutical Industry (APBI). They will pay compensation where the injury probably resulted from the treatment being tested or administered as part of the study protocol, or any test or procedure you received as part of the study. Any payment would be without legal commitment (Please ask if you wish more information on this). They are not bound to pay compensation where:

- the injury resulted from a drug or procedure outside the study protocol;
- the protocol was not followed.

Will I have to sign anything?

Adults and parents/carers who want to join the study and are eligible 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 Fulltec AG, their partner companies, or by regulatory authorities, and NHS 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 Fulltec AG 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 a head louse treatment over the counter from your pharmacy.

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, Fulltec AG.

The results of the study will eventually be made public on the company website or 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 Cambridgeshire 1 Research Ethics Committee.

Contact for further information:

If you would like to take part in this study please call [Elizabeth Brunton](#) or another member of the study team on [01223 813696](#) or [08454 300 300](#). 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 Sheet (6-10)

Looking at a shampoo for head lice

Lots of children in Europe use Fulltec Anti-Lice Protector on their hair to kill lice. If you have head lice we would like you to help us to see how quickly it works? We are going to see if it works in 15 minutes.

Joining is voluntary. If you want to help you must have head lice. We shall visit you at home and comb your hair to make sure before we treat you.



The first part of treatment is to wash and dry your hair. Then we shall the put shampoo onto the damp hair and make a thick foam. Afterwards it will be rinsed off. We will ask your Mum, Dad or the person who looks after you to help. The shampoo treatment is used twice so the same treatment will be put on 8 days later.



The whole study lasts 17 days. In that time, other people will visit you at home on 3 different days to see if there are any lice left. They will comb your hair with a plastic louse comb.

The visits will be made at times to suit you.

We shall give you a different treatment if you still have lice at the end.

Do 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.

Medical Entomology Centre



6 Quay Court, Colliers Lane, Stow-cum-Quay, Cambridge, CB25 9AU

Tel: 08454 300300 or 01223 813696

Fax: + 01223 810078

www.insectresearch.com

info@insectresearch.com