

An investigation of the activity of Fulltec Anti-Lice Protector in the treatment of head lice

Submission date 19/04/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 24/05/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/02/2021	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Head lice are tiny insects that live in hair. They are a common problem, particularly among school-age children. Head lice are spread by direct head to head contact. Although they are harmless, the bites of these lice can cause itching and can be very frustrating for sufferers. Fulltec Anti-Lice Protector is a shampoo based on vegetable oils that is claimed to kill lice by blocking spiracles, usually applied for 15-30 minutes. The aim of this study is to test the effectiveness of Fulltec Anti-Lice Protector in the treatment of head lice using a shortened application time

Who can participate?

People aged 2 years and over who have head lice.

What does the study involve?

Each consenting participant with confirmed louse infestation is treated by applying the Fulltec Anti-Lice Protector to pre-washed and towel dried hair and left for 15 minutes, rinsed and dried to check that this application time is long enough to be effective. This procedure is repeated after 8 days. The presence of headlice are then looked for by combing to look for lice on days 1, 8, and 16 after the initial treatment.

What are the possible benefits and risks?

If the treatment regimen is successful participants benefit from getting rid of their head lice completely. There is a small risk that some participants may experience irritation of the scalp from the shampoo or dryness of the skin afterwards.

Where is the study run from?

Medical Entomology Centre, Cambridge (UK)

When is study starting and how long is it expected to run for?

January 2010 to July 2011

Who is funding the study?

Fulltec AG, Zug, (Switzerland)

Who is the main contact?

Mr Ian F Burgess

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

CTFT01

Study information

Scientific Title

A single centre, single arm, non randomised study to investigate the activity of Fulltec Anti-Lice Protector in the treatment of head lice

Study objectives

The aim of this study is to provide evidence of the activity of Fulltec Anti-Lice Protector in the treatment of head louse infection using a shortened application time (15 minutes).

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridgeshire 1 Research Ethics Committee approved on 03/03/2011, ref: 10/H0304/95

Study design

Single-centre single-arm non-randomised proof of concept study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Head louse infestation

Interventions

Fulltec Anti-Lice Protector shampoo applied to pre-washed and towel dried hair for 15 minutes followed by rinsing, with a repeat treatment 8 days later.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Fulltec Anti-Lice Protector

Primary outcome(s)

Cure of infestation, defined as no evidence of head lice, assessed between completion of the second application of treatment on day 8 and day 16 (the first treatment being applied on day 0).

Key secondary outcome(s)

1. Safety of the product monitored by observation for adverse events on days 0, 1, 8, and 16 of the study
2. Acceptability of the product, assessed by a questionnaire at day 1

Completion date

09/07/2011

Eligibility

Key inclusion criteria

1. Both males and females, aged 2 years and over with no upper age limit
2. People who upon examination, are confirmed to have live head lice
3. People who give written informed consent, or if the 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 follow-up visits by study team members over the 16 days following first treatment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

31

Key exclusion criteria

1. People with a known sensitivity to nuts, coconut, or any of the ingredients in Fulltec Anti-Lice Protector
2. People with a secondary bacterial infection of the scalp (e.g. impetigo) or who have an active long-term scalp condition (e.g. psoriasis of the scalp)
3. People who have been treated with other head lice products within the previous two weeks
4. People who have been treated with the antibiotics co-trimoxazole or trimethoprim within the previous four weeks, or who are currently taking such a course
5. Pregnant or nursing mothers
6. People who have participated in another clinical study within one month before entry to this study
7. People who have already participated in this clinical study

Date of first enrolment

01/04/2011

Date of final enrolment

01/06/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Medical Entomology Centre

Cambridge

United Kingdom

CB25 9AU

Sponsor information

Organisation

Fulltec AG (Switzerland)

ROR

<https://ror.org/02g1dfh62>

Funder(s)

Funder type

Industry

Funder Name

Fulltec AG (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan

The current 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?
Results article	results	02/12/2020	12/02/2021	Yes	No
Participant information sheet	version V1	13/01/2011	03/02/2017	No	Yes
Participant information sheet	version V1	17/01/2011	03/02/2017	No	Yes