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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

Registration date
24/05/2011

Overall study status
Completed

Last Edited
12/02/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 prescence 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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).

Secondary outcome measures
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

Overall study start date
26/01/2010

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

Age group
Adult

Sex
Both

Target number of participants
30

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

England

United Kingdom

Study participating centre
Medical Entomology Centre
Cambridge
United Kingdom
CB25 9AU

Sponsor information

Organisation
Fulltec AG (Switzerland)

Sponsor details
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Sponsor type
Industry

Website
http://www.fulltec.ch/

ROR
https://ror.org/02g1dfh62

Funder(s)

Funder type
Industry

Funder Name
Fulltec AG (Switzerland)

Results and Publications

Publication and dissemination plan
Publication deferred by sponsor after which the company broke up and restructured. Investigators plan to publish in a peer reviewed journal.

Intention to publish date
31/12/2017

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?
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
Results article	results	02/12/2020	12/02/2021	Yes	No