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Shampoo to prevent head lice

Submission date	Recruitment status	[X] Prospectively registered
30/04/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/10/2020	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Head lice are tiny insects that live in human hair and are particularly common in children. They are spread though head-to-head contact. The infestation can cause a person's scalp (head) to itch. This itching isn't due to the insect biting, but rather an allergy to the lice. The aim of this study is to see if Elimax shampoo can prevent or limit the risk of being infested with head lice.

Who can participate?
Participants can be enrolled in the study if they attend school. They can be of any age but have to be the youngest eligible member of their household. They also have to be at risk of head lice infestation.

What does the study involve?
All participants are first checked for lice using a fine-toothed plastic detection comb and treated with Elimax lotion to ensure that they are free from infestation. Each participant is then randomly allocated into one of two groups. Those in group 1 (intervention) are given Elimax shampoo for six weeks. They have to use the shampoo every time they wash their hair and make sure than they do so at least twice a week. Those in group 2 (control) are given a placebo shampoo. They are asked to use it every time they wash their hair for the next 6 weeks and do so at least twice a week. Starting from day 7, participants are checked for lice infestation once a week using the detection comb for the 6 week period . A further treatment with the shampoo is provided if a participant is found to be infested during that time. After 6 weeks, the treatment for both groups is stopped for 7 days for what is known as a "wash out" period. The participants are then treated with Elimax lotion again before "crossing over" for the next 6 weeks, whereby group 1 is now given the placebo shampoo and group 2 Elimax shampoo.

What are the possible benefits and risks of participating?
The benefits of the study are that each participant and their family will have professional supervision and treatment of any head louse infestation risk for a period of 13 weeks, with elimination of any infestation during that time. In terms of risks the only one identifiable is that participants may find they have a previously unidentified sensitivity to sesame and its products.

Where is the study run from?
Medical Entomology Centre (Cambridge)

When is the study starting and how long is it expected to run for?
April 2015 to August 2015

Who is funding the study?
Oystershell NV (Belgium)

Who is the main contact?
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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
CTOY01

Study information

Scientific Title
A randomised, double-blind, cross-over, placebo controlled clinical trial to demonstrate the effectiveness of a product designed to protect against establishment of a head louse infestation.

Study objectives

To demonstrate the proof of concept that Elimax shampoo is effective in preventing or limiting the risk of development/growth of an infestation with head lice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
This is a study of a CE-marked medical device, which has not been modified and is not being used outside of its CE mark intended purpose. Consequently, under the current approach of the UK National Research Ethics Service such a study does not require ethics approval.

Study design
Single-centre randomised double-blind cross-over placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Head louse infestation (pediculosis capitis)

Interventions
Elimax shampoo and placebo shampoo. Both preparations will be applied in the same way as a conventional hair washing shampoo by the parent/carer. All participants are first treated using Elimax lotion to ensure they are free from infestation. The intervention product is used as a replacement for normal shampoo, meaning that the product needs to be used each time the hair is washed. If the hair is normally washed less frequently than twice each week, the preparation should be reapplied after a maximum of 3 days (i.e. the product is applied at least twice each week). The product is used as a regular shampoo, meaning that it is massaged thoroughly into wet hair and afterwards the hair is rinsed with water. Each product is used for 6 weeks followed by a one week break during which a second treatment with Elimax lotion is provided to ensure louse free status before cross-over to the other intervention. Participants are monitored once each week by detection combing for presence of lice and if infested a further lotion treatment provided.

Intervention Type
Other

Primary outcome measure
Time to first infestation of head lice during the six week period of treatment

Secondary outcome measures
Secondary endpoints are:
1. Whether an infestation occurred during either of the the six week treatment periods (active or placebo)
2. The number of infestations occurring during either of the treatment periods

Overall study start date
30/04/2015

Completion date
30/08/2015

Eligibility

Key inclusion criteria
1. Potential participants attending school with no upper age limit, although they must be the youngest qualifying member of the household
2. Potential participants who upon examination, are confirmed to be at risk of infestation with head lice
3. Potential participants 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. Potential participants who will be available for home visits by MEC study team members over the 13 weeks of the study

Participant type(s)
Healthy volunteer

Age group
Child

Sex
Both

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
1. Potential participants with a known sensitivity to sesame, sesame oil, any of the ingredients in Elimax shampoo, Elimax lotion or the placebo shampoo preparations
2. Potential participants with a secondary bacterial infection of the scalp (e.g. impetigo) or who have a long term scalp condition (e.g. psoriasis of the scalp)
3. Pregnant or nursing mothers

4. Potential participants who have participated in another clinical study within 1 month before entry to this study
5. Potential participants who have already participated in this clinical study

Date of first enrolment
01/05/2015

Date of final enrolment
30/05/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Medical Entomology Centre
Insect Research & Development Limited
6 Quy Court, Colliers Lane
Stow-Cum-Quy
Cambridge
United Kingdom
CB25 9AU

Sponsor information

Organisation
Oystershell NV

Sponsor details
Booiebos 24
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B-9031

Sponsor type
Industry

ROR
https://ror.org/000ad3960

Funder(s)

Funder type
Industry

Funder Name
Oystershell NV (Belgium)

Results and Publications

Publication and dissemination plan
There are no definite plans for publication or dissemination of the results at this stage, which will, in any case, be subject to the approval of the sponsor. However, it is hoped that the data can be published in a suitable peer-reviewed journal.

Intention to publish date

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		19/10/2020	23/10/2020	No	No