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How well does the plastic detection comb (PDC) remove nits?

Submission date
10/10/2014

Recruitment status
No longer recruiting

Registration date
31/10/2014

Overall study status
Completed

Last Edited
02/09/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
When combing to help remove old louse eggs and nits, many people would like a comb that is more comfortable to use and does not damage hair like some of the metal combs. The plastic detection comb (PDC) is widely used for detection of louse infestation but can also remove louse eggs. This study is to find out how effective it is for removing louse eggs and nits from damp hair.

Who can participate?
Anyone over 4 years of age who has had head lice and currently has louse eggs or empty eggshells attached to the hair could take part.

What does the study involve?
Taking part in the study will usually last about 30 minutes. However, for anyone who has an active head louse infestation we can provide a treatment for that before combing the hair. The combing is performed on damp hair after hair washing and involves counting of louse eggs and nits on a selected section of hair followed by 10 strokes of the plastic comb through that section of hair to remove the eggshells. Any eggs and nits not removed will be counted after combing. The eggs and nits are removed will be collected on a tissue and then fixed into the record form for counting.

What are the possible benefits and risks of participating?
The possible benefit of the study is that participants with an infestation could get rid of their head lice without charge. The possible risks of the study is slight discomfort during combing.

Where is the study run from?
Medical Entomology Centre, Insect Research & Development Limited, UK.

When is the study starting and how long is it expected to run for?
March 2014 to July 2015

Who is funding the study?
KSL Consulting, Denmark

Who is the main contact?
Mr Ian Burgess
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CTKL01

Study information

Scientific Title
A proof of concept investigation to evaluate the effectiveness of the plastic detection comb (PDC) comb, a Class I medical device, for removal of head louse eggs and nits

Study objectives
Many people would like to find a comb to help remove old louse eggs and nits that is more comfortable to use and does not damage hair like some of the metal combs. The PDC comb is widely used for detection of louse infestation but can also remove louse eggs. This trial is to find out how effective it is for removing louse eggs and nits from damp hair.

Ethics approval required

Old ethics approval format

Ethics approval(s)
West of Scotland REC 4; 17/04/2014; ref: 14/WS/0080

Study design
Observational proof of concept study from one study site

Primary study design
Observational

Secondary study design
Single-centre

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 (Pediculus humanus capitis) infestation

Interventions
Current interventions as of 22/05/2017:
Each participant is first checked for presence of head louse eggs and/or nits. If an active head louse infestation is present they were treated using a standard of care product, in which case the combing was deferred for another day so the treatment could be adequately washed out.

For the study treatment the hair is washed or wetted and straightened using a normal comb. A section of hair was then selected extending from the crown of the scalp so that:
-The number of eggshells on the hair could be observed and estimated with some degree of confidence as to the actual numbers
-Combing could be performed with clearly defined, straight pulls of the comb
-The comb could be inserted into the hair to engage with the scalp to bring the full depth of the hair within the teeth
-The alignment of the comb against the skin, to bring the hairs as close to the base of the teeth as possible, was more ergonomically successful
-The process could be watched carefully to ensure that the eggshells were engaged and that they were not lost as the comb was withdrawn from the hair.

Ten strokes of the comb are made through this section of hair and any louse eggs/nits removed are collected on a medical wipe tissue. After 10 strokes of the comb the number of louse eggshells remaining are observed and counted as are the number removed.

Previous interventions:
Combing with the PDC comb, which is a plastic fine-toothed comb made from Acrylonitrile

butadiene styrene
(ABS) with a tooth gap of approximately 0.23 mm.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measure as of 22/05/2017:
The efficiency of the comb to remove louse eggs and nits is defined the proportion of those louse eggs and nits found on a section of hair using 10 strokes of the comb.

Previous primary outcome measures:
Removal of head louse eggs and nits from the hair. The measure of efficiency will be the proportion of the eggs within a delineated section of hair being removed by 10 strokes of the comb.

Secondary outcome measures
Ease of use and acceptability of the combing regimen. These will be taken during the process of the intervention, i.e. the ease of use is a subjective observation by the investigator, and the acceptability will also be assessed subjectively by simply asking the participant whether the process is comfortable or uncomfortable, so baseline will be the time point with the whole procedure completed within 10 minutes.

Overall study start date
03/03/2014

Completion date
08/07/2015

Eligibility

Key inclusion criteria
1. People aged 4 years and over with no upper age limit
2. People who, upon examination, are confirmed to have head louse eggs and/or nits present in their hair
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

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Sex
Both

Target number of participants
25 participants

Key exclusion criteria
1. People with a secondary bacterial infection of the scalp (e.g. impetigo) or who have an active long-term scalp condition other than head lice (e.g. psoriasis of the scalp)
2. Pregnant or nursing mothers
3. People who have already participated in this clinical study

Date of first enrolment
30/03/2014

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Insect Research & Development Limited
6 Quy Court
Colliers Lane
Stow-cum-Quy
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Sponsor information

Organisation
KSL Consulting (Denmark)

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Sponsor type
Industry

Website
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ROR
https://ror.org/0279am519

Funder(s)

Funder type
Industry

Funder Name
KSL Consulting (Denmark)

Results and Publications

Publication and dissemination plan
There are currently no plans to publish the outcomes of this study.

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Burgess at ian@insectresearch.com

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No