

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

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<b>Registration date</b> 31/10/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/09/2020	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

ian@insectresearch.com

## Contact information

### Type(s)

Scientific

### Contact name

Mr Ian Burgess

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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 Quay Court  
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**Sponsor information****Organisation**

KSL Consulting (Denmark)

**Sponsor details**

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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](mailto: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?
<a href="#">HRA research summary</a>			28/06/2023	No	No