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A new treatment for head lice? Efficacy of Nice 'n Clear and 'ClearBrush' for nit removal

Submission date
07/11/2007

Recruitment status
No longer recruiting

Registration date
05/02/2008

Overall study status
Completed

Last Edited
30/10/2019

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. Nits are the empty egg cases attached to hair that head lice hatch from. There are several different products (insecticides) that can be applied to the scalp and hair to kill head lice. Some head louse treatments are not effective because they are difficult to use or the lice are resistant to the insecticide. The original formula Nice ‘n Clear head lice lotion (ONC) was conditioner-based and not effective to eliminate lice but it was good as a combing aid. This study tests a lotion containing neem oil, believed to be an active material to coat the lice (new formula Nice ‘n Clear), and compares it with an isopropyl myristate and silicone-based product (Full Marks solution). The study also looks at a new way to remove louse eggs and nits using an ultrasound comb (Clearbrush). The effectiveness of the comb is assessed using new formula Nice ‘n Clear in comparison with original Nice ‘n Clear.

Who can participate?
Anyone over 4 years of age who has head lice

What does the study involve?
Participants are randomly allocated to receive one of four treatments: new formula Nice ‘n Clear, Full Marks solution, Clearbrush and new formula Nice ‘n Clear, or Clearbrush and original formula Nice ‘n Clear. All treatments are applied on the first day, with repeat treatment after 7 days, and there are four follow-ups over 2 weeks to see how well they work.

What are the possible benefits and risks of participating?
The possible benefit of the study is that patients could get rid of their head lice without charge. The possible risks of the study are discomfort or irritation where the treatment is applied either during or after the treatment, or pulling of the hair 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?
September to December 2007

Who is funding the study?
Sixth Framework Programme

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
Protocol CTNC02, Version: 1.0, 20 February 2007

Study information

Scientific Title
A randomised, assessor-blinded clinical study to compare the efficacy and safety of Nice 'n Clear with Full Marks solution and to evaluate a novel ultrasound comb device 'ClearBrush' for removal of nits

Acronym
ClearBrush

Study objectives
This study has two elements; in the first a comparison will be made of the silicone-based Nice 'n Clear with that of Full Marks solution. At the same time ClearBrush will be evaluated for efficacy at removing louse eggs and nits using both the new formulation of Nice 'n Clear and the original formulation.

The data obtained from the comparison of Nice 'n Clear with Full Marks solution and the data obtained in the earlier CTNC01 study will be used as baseline data for comparing the efficacy of ClearBrush to facilitate louse egg removal using each of these lubricants. Safety, ease of application, and participant acceptability of each of the products will also be assessed.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 Research Ethics Committee, 20/06/2007, ref: 07/Q0104/44

Study design
Randomised single-blind (assessor-blind) parallel-group comparative multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

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

Interventions
1. Herbal-based (neem oil, with tea tree, thyme and lemongrass essential oils) lotion in a silicone vehicle (reformulated Nice 'n Clear lotion) (66 participants)
2. Isopropyl myristate/cyclomethicone lotion (Full Marks solution) (66 participants)
3. ClearBrush ultrasound nit-removing comb in combination with herbal-based lotion in an aqueous cream vehicle (original Nice 'n Clear head louse treatment lotion) (22 participants)
4. ClearBrush ultrasound nit-removing comb in combination with herbal-based lotion in a silicone vehicle (reformulated Nice 'n Clear lotion) (22 participants)

The total time for intervention and follow-up for each participant is 15 days, two treatments a week apart with a follow-up 2 and 6 days after the first treatment and 2 and 7 days after the second treatment.

Intervention Type
Other

Primary outcome measure
1. Efficacy of using reformulated Nice 'n Clear lotion in comparison with Full Marks solution to cure an infection, i.e. no lice at the days 9 and 14 assessments
2. Efficacy of the ClearBrush in use with the new and the original Nice 'n Clear head lice treatment preparations, measured using data obtained from each treatment, i.e. on days 7 and 14

Secondary outcome measures
Safety and acceptability of the Nice n Clear preparations and Full Marks solution, measured at the end of the 15 days

Overall study start date
13/09/2007

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Male and female participants who are found to have an active head louse infection, i.e. the presence of live lice. Detection combing will be done with a fine-toothed plastic detection comb, until at least one louse is found. Any lice found at these assessments will not be removed
2. Participants who give written informed consent and/or, if the participant is below 16 years of age, whose guardian gives written informed consent to participate in the study. An assent form will be required for those between the ages of 4 and 16 years of age. There is no maximum age limit. The lower age limit for this study will be 2 years (Nice 'n Clear is marketed as a medical device for babies and children down to the age of 6 months and Full Marks solution for children down to 2 years)
3. Participants must be available for the duration of the study, i.e. 15 days

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
176

Total final enrolment
134

Key exclusion criteria
1. Participants who have been treated with other head louse products within the previous 2 weeks (14 days)
2. Participants who have undergone a course of antibiotic treatment using Cotrimoxazole, Trimethoprim or Septrin within the previous 4 weeks, or who are currently taking such a course
3. Participants whose hair has been bleached, colour treated, or semi-permanently waved within the previous 2 weeks; this includes the use of semi-permanent colouring agents. Home use wash in/wash out colouring agents are acceptable.
4. Participants who have taken part in another clinical study within 4 weeks prior to entry to this one
5. Female participants who are pregnant or breastfeeding
6. Participants who have already taken part in this study
7. Participants who have a known allergy to any of the ingredients of either of the Nice 'n Clear preparations or Full Marks solution (including allergy to Paraben preservatives)
8. Children under 2 years of age

Date of first enrolment
13/09/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Insect Research & Development Limited
Royston
United Kingdom
SG8 6QZ

Sponsor information

Organisation
Nelsons (UK)

Sponsor details

Nelsons House
83 Parkside
Wimbledon
London
United Kingdom
SW19 5LP

Sponsor type
Industry

Website
http://www.nelsons.net/corporate_home

Funder(s)

Funder type
Government

Funder Name
Sixth Framework Programme (contract number: 017916-ClearBrush)

Alternative Name(s)
EC Sixth Framework Programme, European Commission Sixth Framework Programme, EU Sixth Framework Programme, European Union Sixth Framework Programme, EU 6th Framework Programme, European Union 6th Framework Programme, 6th EU Research Framework Programme, European Union's Sixth Framework Programme, The 6th EU Research Framework Programme, 6th FP, EUROPEAN UNION'S 6TH FRAMEWORK PROGRAMME, 6th Framework Programme, EC Framework Programme 6, FP6

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The manuscript describing the study is currently in press.

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request from Mr Ian Burgess (ian@insectresearch.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2017	30/10/2019	Yes	No