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Is Liceko® more effective than Nix® / Lyclear® against head lice?

Submission date	Recruitment status	[X] Prospectively registered
19/04/2011	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/05/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/09/2013	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CTPN01

Study information

Scientific Title
A randomised, controlled, assessor-blind, clinical trial to compare Liceko® with Nix® / Lyclear® 1% permethrin creme rinse in the treatment of head lice.

Study objectives
To confirm that Liceko® is effective to kill head lice and their eggs using two applications in comparison with two applications of Nix® / Lyclear®, and to identify any significant difference in performance (superiority) of one product over the other in the eradication of head lice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-centre randomised two-arm comparative 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 below to request a patient information sheet

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

Interventions
Group A Liceko®: The product will be applied directly to dry hair. Sufficient product will be applied to saturate the hair and scalp. The product will be left in place for 20 minutes before being shampooed and rinsed off with water.

Group B Nix® / Lyclear® : The product will be applied to washed and towel dried hair. Sufficient product will be applied to saturate the hair and scalp. The product will be left in place for 10 minutes before being rinsed off with water.

For both treatments the product will be reapplied at Day 7.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Cure of infestation, defined as no evidence of head lice, assessed between completion of the second application of treatment on day 7 and day 14 (the first treatment being applied on day 0).

Secondary outcome measures
1. Comparison of the efficacy of Liceko® with that of Nix® / Lyclear® crème rinse and to identify superiority of one product over the other if appropriate.
2. Safety of the products monitored by observation for adverse events on days 0, 1, 6, 7, 9, and 14 of the study

Overall study start date
01/07/2011

Completion date
31/10/2011

Eligibility

Key inclusion criteria
1. Both males and females, aged 6 months 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 14 days following first treatment

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Sex
Both

Target number of participants
44 divided into two groups of 22

Key exclusion criteria

1. People with a known sensitivity to any of the ingredients in Liceko ® or Nix® / Lyclear® 1% permethrin creme rinse, pyrethroid insecticides, or plants related to dandelions or chrysanthemums.
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 bleached hair, or hair that has been permanently waved within the previous four weeks
5. 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
6. Pregnant or nursing mothers
7. People who have participated in another clinical study within one month before entry to this study
8. People who have already participated in this clinical study

Date of first enrolment
01/07/2011

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Panin S.R.L (Italy)

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Sponsor type
Industry

Website
http://www.panin.it/

ROR
https://ror.org/00c5hbd86

Funder(s)

Funder type
Industry

Funder Name
Panin S.R.L (Italy)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/09/2013		Yes	No