

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

Submission date 19/04/2011	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 24/05/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/09/2013	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Sex

All

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

United Kingdom

England

Study participating centre

Medical Entomology Centre

Cambridge

United Kingdom

CB25 9AU

Sponsor information

Organisation

Panin S.R.L (Italy)

ROR

<https://ror.org/00c5hbd86>

Funder(s)

Funder type

Industry

Funder Name

Panin S.R.L (Italy)

Results and Publications

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