Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison effect of permethrin shampoo to permethrin shampoo with vinegar in the treatment of head lice in children aged 6-13 years

Protocol summary

Study aim
Comparison effect of permethrin shampoo to permethrin shampoo with vinegar in the treatment of head lice in children aged 6-13 years

Design
A clinical trial with a control and intervention group, without blinding, randomized using a table of random numbers, on 110 patients.

Settings and conduct
This study is conducted in the medical centers in the suburbs of Tehran and with patients referred to these centers. After entering, the clients are examined and the patients who are satisfied to participate in the study are divided into two intervention and control groups with a table of random numbers. The intervention group is treated with "permethrin shampoo and vinegar-soaked comb" and the control group is treated with "permethrin shampoo" for two weeks. At the end of two weeks, the patients are examined again and the results are analyzed statistically.

Participants/Inclusion and exclusion criteria
Conditions for entering the study: All children aged 3 to 6 who have head lice. Conditions for not entering the study: Those who have received anti-insect treatment in the past month. Children who have an underlying disease. Children whose parents are not fluent in Persian Children who do not consent to participate in the study Children whose parents did not sign the written consent form Children who are allergic to vinegar or permethrin shampoo. The family population and the density of people in the patient's house should not be normal Other family members have symptoms of head lice.

Intervention groups
Intervention group: combined use of permethrin shampoo as a common treatment and comb soaked in vinegar

Main outcome variables
infection with head lice, head lice betterment, Use of permethrin, Using a comb dipped in vinegar

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110420006243N5**
Registration date: **2024-09-18, 1403/06/28**
Registration timing: **prospective**

Last update: **2024-09-18, 1403/06/28**
Update count: **0**

Registration date
2024-09-18, 1403/06/28

Registrant information

Name
Shiva Rafati

Name of organization / entity
Shahed university

Country
Iran (Islamic Republic of)

Phone
+98 21 8896 9437

Email address
rafati@shahed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-09-22, 1403/07/01

Expected recruitment end date
2025-03-19, 1403/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effect of permethrin shampoo to permethrin shampoo with vinegar in the treatment of head lice in children aged 6-13 years

Public title
The effect of vinegar in the treatment of head lice

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All children aged 3 to 6 who have head lice

Exclusion criteria:
Those who have received anti-insect treatment in the past month. Children who have an underlying disease. Children whose parents are not fluent in Persian Children who do not consent to participate in the study Children whose parents did not sign the written consent form Children who are allergic to vinegar or permethrin shampoo. The family population and the density of people in the patient's house should not be normal Other family members have symptoms of head lice.

Age
From **3 years** old to **6 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
A simple randomization method using the roll of a die method. For each of the clients whose head lice diagnosis is certain, a dice is thrown separately and in this method, even numbers are assigned to the control group and odd numbers are assigned to the intervention group, and based on this, the clients are divided into two control and intervention groups. they turn

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features
First, all the children aged 6 to 13 who have visited the treatment center are examined by trained people, and among them, children with head lice are included in the study after the parents fill in the written informed consent form and the child's basic information questionnaire.Then we divide them into intervention and control groups using a random number table. The people in the two groups should be the same in terms of age, gender, severity of the disease and the number of family members.Then the parents of both groups should be trained about the treatment protocol, intervention protocol and health protocol

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahed University

Street address
Persian Gulf Highway

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2024-03-09, 1402/12/19

Ethics committee reference number
IR.SHAHED.REC.1402.137

Health conditions studied

1

Description of health condition studied
pediculosis capitis

ICD-10 code
B85.0

ICD-10 code description
Pediculosis due to Pediculus humanus capitis

Primary outcomes

1

Description
infection with head lice

Timepoint
Head examination of children for head lice before the intervention and 14 days after the intervention, using permethrin and vinegar shampoo.

Method of measurement
Examination of children's heads by qualified experts

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Combined use of permethrin shampoo as a common treatment and vinegar-soaked comb

Category
Treatment - Other

2

Description
Control group: Geting permethrin shampoo as a common treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mostafa Khomeini hospital
Full name of responsible person
Amirparsa Khalili
Street address
Italy street
City
Tehran
Province
Tehran
Postal code
1416645151
Phone
+98 21 8899 7163
Email
info@mkht.ir
Web page address
http://mkht.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Dr.Reza Forouzanfar
Street address
Persian Gulf Highway
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Email
publicrelation@shahed.ac.ir
Web page address
https://shahed.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University
Proportion provided by this source
20
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Amirparsa Khalili
Position
student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All potential data is shareable after de-identifying individuals.
When the data will become available and for how long
Beginning of the information access period: 6 months after the results are published
To whom data/document is available
Researchers working in related academic and scientific institutions
Under which criteria data/document could be used
Those who want to use the data and documents of this study. Must apply via email. After reviewing their request and the reason for their need for information and the approval of the research team, the information will be sent.
From where data/document is obtainable
People should explain the reason for the request, the need for information and the type of analysis they want to do on the data through an email to amirparsakhalili92@gmail.com.
What processes are involved for a request to access data/document
Individuals should explain the reason for the request, the reason for needing the information and the type of analysis they want to perform on the data in an email. Their request has been reviewed by the research team. And after the approval of the research team, the information will be sent.
Comments