

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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: Getting 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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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

Medical doctor

Other areas of specialty/work

General Practitioner

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Web page address<http://mkht.ir/>**Person responsible for updating data****Contact****Name of organization / entity**

Shahed University

Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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Web page address<http://mkht.ir/>**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