

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluating the effectiveness of topical permethrin with three different methods for treating head lice

Protocol summary

Study aim

comparison of therapeutic effects of administration of three different regimes for head lice treatment

Design

Randomized, controlled trial, involving 90 people in 3 parallel groups (30 patients in each group), Sealed Envelope web service was used for block randomization (www.sealedenvelope.com). Due to the fact that the patient's family must be treated in case of infestation, other family members will also be in the allocation group of the main patient.

Settings and conduct

Recruitment were done in several urban pharmacies in Tehran. Patients requesting head lice treatment after examination and confirmation of live lice (nymph or mature lice) were invited to signed the written inform consent, and if they accept the conditions, based on block randomization they were divided into three groups. Response to treatment was performed by an expert who was blinded to the groups.

Participants/Inclusion and exclusion criteria

Patients with head lice over 6 years of age who had not been treated for the infection before, were included in the study, and those with a history of allergy to topical permethrin products, pregnant women, lactating patients, and patients with a history of asthma and seizures were excluded.

Intervention groups

The first group receives permethrin shampoo that stays on the head for 10 minutes according to the instructions. The second group receives permethrin shampoo that stays on the head for one hour according to the instructions. The third group receives permethrin cream rinse that stays on the head for 10 minutes according to the instructions.

Main outcome variables

1) Visualization of live headlice: Examination of the scalp using the dry combing method 2) Scalp pruritus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170608034390N8**

Registration date: **2021-11-14, 1400/08/23**

Registration timing: **retrospective**

Last update: **2021-11-14, 1400/08/23**

Update count: **0**

Registration date

2021-11-14, 1400/08/23

Registrant information

Name

Hadi Esmaily

Name of organization / entity

SBMU

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of topical permethrin with three different methods for treating head lice

Public title

Evaluating three different regimes of permethrin in head lice treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with head lice infestation Up than 6 years old

Exclusion criteria:

History of allergy or side effects with permethrin shampoo or permethrin cream Pregnant Women Lactating Women History of Asthma History of hypersensitivity reaction to permethrin History of seizure Active wounds in scalp

Age

From **6 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done using the block randomization method. To do this, 10 blocks of 9 people were prepared in the Sealed Envelope online software (www.sealedenvelope.com) and 30 patients were placed in each group. Due to the fact that the patient's family must be treated in case of infestation, other family members will also be in the allocation group of the main patient. More Details: To create this list, we consider the number of block sizes as 9 and the list length as 90, in the treatment groups section, we enter three groups: Group A, Group B and Group C, in which case the software generates 10 blocks with 9 options. Out of a total of 90 codes, 30 will be Group A, 30 will be Group B, as well as 30 in Group C.

Blinding (investigator's opinion)

Single blinded

Blinding description

The expert who examines the response to the interventions and the statistical analyzer is blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National ethics committee for biomedical research

Street address

Central Department of Ministerial of Health and Medical Education, Sima Iran St, between South Falamak and Zarafshan St, Shark Gharb

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-07-15, 1398/04/24

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.109

Health conditions studied**1****Description of health condition studied**

Head lice

ICD-10 code

B85.0

ICD-10 code description

Pediculosis due to *Pediculus humanus capitis*

Primary outcomes**1****Description**

Presence of live lice (both adult and nymph) using the

Timepoint

First week, Second week, third week

Method of measurement

Dry combing method

Secondary outcomes**1****Description**

Time to eradication

Timepoint

First week, Second week, Third week

Method of measurement

Time (Date)

Intervention groups

1

Description

Intervention group: Received permethrin shampoo that stays on the head for 10 minutes according to the instructions.

Category

Treatment - Drugs

2

Description

Intervention group: Received permethrin shampoo that stays on the head for one hour according to the instructions.

Category

Treatment - Drugs

3

Description

Intervention group: Received permethrin cream rinse that stays on the head for 10 minutes according to the instructions.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr Hadi Esmaily Pharmacy

Full name of responsible person

Hadi Esmaily Pharm.D.

Street address

Dr Hadi Esmaily pharmacy, Golestan St., Shahid Bagheri Town, East Hemat Highway

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2

Recruitment center

Name of recruitment center

Dr Arman Sadat Mansoury Pharmacy

Full name of responsible person

Arman Sadat Mansoury Pharm.D

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Dr Arman Sadat Mansoury pharmacy.7th East Alley corner.24metri Blvd.Farhang sq.saadat abad

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3

Recruitment center

Name of recruitment center

Kokh Pharmacy

Full name of responsible person

Yashar Hatamzadeh Pharm.D

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti university of medical sciences, taleghani hospital, shahid arabi st, yemen ave, shahid chairman highway

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1985717443

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Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

Public or private sector

Private

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Hadi Esmaily

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Email**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Aida Edalatkhah Tatafi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

the whole potential data is unpublished after being unidentifiable.

When the data will become available and for how long

start the access period 6 month after pricing the result

To whom data/document is available

researchers working in academic and industrial institutions.

Under which criteria data/document could be used

it can be used to carry out research work.

From where data/document is obtainable

Dr Hadi Esmaily, faculty of pharmacy, shahid beheshti university of medical science

What processes are involved for a request to access data/document

sending request is available.

Comments

