

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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](http://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)

##### Phone

+98 21 8887 3704

##### Email address

[esmaily\\_hadi@sbmu.ac.ir](mailto:esmaily_hadi@sbmu.ac.ir)

##### 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](http://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

##### City

Tehran

##### Province

Tehran

##### Postal code

1495914978

##### Phone

+98 21 4473 1443

##### Email

Esmaily\_hadi@sbmu.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Dr Arman Sadat Mansoury Pharmacy

##### Full name of responsible person

Arman Sadat Mansoury Pharm.D

##### Street address

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

#### City

Tehran

#### Province

Tehran

#### Postal code

1997756863

#### Phone

+98 21 2208 7244

#### Email

DrArman\_Pharmacy@yahoo.com

### 3

#### Recruitment center

##### Name of recruitment center

Kokh Pharmacy

##### Full name of responsible person

Yashar Hatamzadeh Pharm.D

##### Street address

Kokh Pharmacy.Dr Qarib st.keshavarz blvd

##### City

Tehran

##### Province

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##### Postal code

1419893163

##### Phone

+98 21 6692 7610

##### Email

yashar.hatamzadeh@gmail.com

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 2243 9780

##### 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

100

esmaily\_hadi@sbm.ac.ir

**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

**Street address**

Shahid Beheshti Pharmaceutical Faculty, Vali Ars Ave

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Tehran

**Province**

Tehran

**Postal code**

1991953381

**Phone**

+98 211579064

**Email**

Esmaily\_hadi@sbm.ac.ir

**Person responsible for scientific 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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**Email**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Aida Edalatkhah Tatafi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Medical Pharmacy

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tehran

**Province**

Tehran

**Postal code**

1991953381

**Phone**

+98 21 8820 0118

**Email**

aida\_alive@yahoo.com

**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**

