

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparing the efficacy of permethrin 1% and dimethicone 4% in treatment of primary school girls with head lice infestation: a clinical trials

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

##### Study aim

Comparing the efficacy of permethrin 1% and dimethicone 4% in treatment of head lice infestation.

Last update: **2018-02-22, 1396/12/03**

Update count: **0**

##### Design

This study is a double blind randomized clinical trial (phase 4) carried out among 90 patients with pediculosis infestation. These patients will be randomly allocated to permethrin 1% and dimethicone 4% treatment groups. Using random allocation software, 15 blocks of six will be prepared and subjects will be entered into the trial based on these blocks.

##### Registration date

2018-02-22, 1396/12/03

##### Registrant information

###### Name

Mahmood Moosazadeh

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3311 9562

###### Email address

mmoosazadeh1351@mazums.ac.ir

##### Settings and conduct

The study is conducted among primary school girls in Goloughah, Mazandaran province.

##### Recruitment status

**Recruitment complete**

##### Funding source

Mazandaran University of Medical Sciences

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Female gender, age between 6 and 13 years, being infected with head lice and having normal general condition. Exclusion criteria : History of any sensitivity to anti-pediculosis drugs, dermatologic disorders, secondary bacterial infection, scalp burning, asthma, using hair care products, using anti-pediculosis drugs during the last seven days.

##### Expected recruitment start date

2018-02-20, 1396/12/01

##### Expected recruitment end date

2018-03-15, 1396/12/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Intervention groups

Group 1 intervention: Lotion dimethicone 4% will be rubbed on the hairs from the root to the top. Group 2 intervention: The total surface of the sculp and hairs will be peeled With appropriate amount of permethrin 1% .

##### Scientific title

Comparing the efficacy of permethrin 1% and dimethicone 4% in treatment of primary school girls with head lice infestation: a clinical trials

##### Main outcome variables

Cure rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171117037512N2**

Registration date: **2018-02-22, 1396/12/03**

**Public title**

Comparing the efficacy of permethrin and dimethicone in treatment of head lice infestation

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Female gender age between 6 and 13 years being infected with head lice having normal general condition

**Exclusion criteria:**

History of any sensitivity to anti-pediculosis drugs  
Dermatologic disorders Secondary bacterial infection  
Scalp burning Asthma Using hair care products Using anti-pediculosis drugs during the last seven days

**Age**

From **6 years** old to **13 years** old

**Gender**

Female

**Phase**

4

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This study is a double blind randomized clinical trial carried out among 90 patients with pediculosis infestation. These patients will be allocated to permethrin 1%(Gilaranco, Rasht, Iran) and dimethicone 4%(Salmi Daru co, Tehran, Iran, IRC: 1228136177) treatment groups using block randomization by means of random allocation software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Both drugs will be covered with similar boxes for blinding reason. This action is enough to blind patients because the shampoo is consumed at home. The outcome evaluators will also be blinded.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Mazandaran University of Medical Sciences

**Street address**

Mazandaran-Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

7678948516

**Approval date**

2015-10-05, 1394/07/13

**Ethics committee reference number**

1488

**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**

Cure rate in each group as no evidence of any adult lice, nymph or egg.

**Timepoint**

Before intervention, days 7, 14 and 21.

**Method of measurement**

Examination of samples by an expert medical entomologist

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

Dermal and periorbital allergic reactions.

**Timepoint**

Before intervention, days 7, 14 and 21.

**Method of measurement**

Sample examination

**Intervention groups****1****Description**

Group 1 intervention: In the treatment group with dimethicone, lotion dimethicone 4% will be peeled around the hairs from the root to the top. It should be normally dried and stayed at least eight hours or one night.

**Category**

Treatment - Drugs

## 2

### Description

Control group: In the treatment group with permethrin 1%, first, hairs will be washed by another shampoo and dried. Then, all hairs as well as the scalp should be completely covered with appropriate amount of permethrin 1% shampoo for 10 minutes and then, will be washed with water.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School

##### Full name of responsible person

Mahmood Moosazadeh

##### Street address

Moallem square, research deputy

##### City

Ghaloughah

##### Province

Mazandaran

##### Postal code

4851676789

##### Phone

+98 11 3448 4800

##### Email

mmoosazadeh1351@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Majid saeedi

##### Street address

Moallem Squire-research deputy

##### City

Sari

##### Province

Mazandaran

##### Postal code

4851676789

##### Phone

+98 11 3448 4800

##### Email

majsaeedi@gmail.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Sari University of Medical Sciences

### Proportion provided by this source

100

### 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

Mazandaran University of Medical Sciences

#### Full name of responsible person

Mahmood Moosazadeh

#### Position

Faculty member

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Epidemiology

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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#### Position

Faculty member

#### Latest degree

Ph.D.

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mahmood Moosazadeh

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Faculty member

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**Phone**

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**Fax****Email**

mmoosazadeh1351@gmail.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

All data will be shared.

**When the data will become available and for how long**

After publishing the results.

**To whom data/document is available**

Researchers working in academic institutions.

**Under which criteria data/document could be used**

To be applied as a data bank for IPD meta-analysis.

**From where data/document is obtainable**

Via e-mail to corresponding author  
mmoosazadeh1351@gmail.com

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

The data will be sent after 10 days.

**Comments**