

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

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Email address

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Settings and conduct

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

Recruitment status

Recruitment complete

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.

Funding source

Mazandaran University of Medical Sciences

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% .

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2018-03-15, 1396/12/24

Main outcome variables

Cure rate

Actual recruitment start date

empty

Actual recruitment end date

empty

General information

Trial completion date

empty

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171117037512N2**

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

Scientific title

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

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

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Moallem square, research deputy

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid saeedi

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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 updating data****Contact****Name of organization / entity**

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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