

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effect of Dimethicone losion with Permethrin shampoo in the treatment of pediculosis in children referred to the children's clinic in Bahar Hospital of Shahroud, a clinical trial

Protocol summary

Study aim

Comparison of the effect of Dimethicone losion with Permethrin shampoo in the treatment of head lice in children

Design

A randomized, triple blind clinical trial, based on children with head lice, which has two parallel groups.

Settings and conduct

The incidence of lice in developing countries is very high at school ages. Of all types of lice, the type of head is more common in children aged 3-12 years old and difficult to control. Many medicines are used to treat head lice, each of which has advantages and disadvantages. Recently, in some studies, the effect of Dimethicone losion on the treatment of head lice has been mentioned, which, in addition to the very good effect, is also very healthy in terms of side effects. Due to the very high prevalence of lice, especially head lice among primary school children, and the need for an effective, safe and safe drug, this study is necessary. This study is a randomized controlled clinical trial that doing in Bahar Hospital of Shahroud.

Participants/Inclusion and exclusion criteria

136 children with head lice who did not have allergic to anti-lice drugs and who did not use them during the last month are included in the study.

Intervention groups

In the intervention group, Dimethicone losion 4% was used to evaluate its effectiveness in head lice. In the control group, Permethrin shampoo 1% was used for the treatment of head lice.

Main outcome variables

The rate of head lice and head itching in the beginning of the study, 7 and 14 days after treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100102002954N14**

Registration date: **2018-11-12, 1397/08/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-12, 1397/08/21**

Update count: **0**

Registration date

2018-11-12, 1397/08/21

Registrant information

Name

Mohammad Bagher Sohrabi

Name of organization / entity

Shahroud University of Medical Ssciences and Health

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-01-20, 1397/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Dimethicone losion with Permitrin shampoo in the treatment of pediculosis in children referred to the children's clinic in Bahar Hospital of Shahroud, a clinical trial

Public title

Comparison of the effect of Dimethicone losion with Permitrin shampoo in the treatment of pediculosis in children

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children infected with head lice; Age 3 to 12 years; Having general health; Parental Satisfaction for Child Participation in the Plan;

Exclusion criteria:

Having autoimmune disease; Having a history of asthma History of using anti-convulsion drugs Use of anti-lice drugs in a recent month Having a scalp wound or scalp burning Having tumors of the scalp Parental no satisfaction for Child Participation in the Plan;

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: use block; Random unit: Individual; Randomization tool: Statistical software; Sequence Building: Using randomized 4 in 4 blocks; Hiding method: Use envelopes in the package

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, participant, antecedents of the outcome evaluation, and analyzer are blinded. The division of patients into two groups A and B is done by a qualified person who has no knowledge of the actions performed in the two groups. Do experiments and results recorder will be done by a qualified person without any knowledge of the type of medicine and patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

Street address

Research Deputy; Shahroud University of Medical Sciences; Haft Tir Square

City

Shahroud

Province

Semnan

Postal code

3614773947

Approval date

2018-05-23, 1397/03/02

Ethics committee reference number

IR.SHMU.REC.1397.034

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

Improvement based on the absence of adult lice, nymphs and lambs (Rashke)

Timepoint

At the beginning of the study, 7 and 14 days after the treatment

Method of measurement

Examination of children with magnifying by a pediatrician

Secondary outcomes

1

Description

Measuring the level of itching of the scalp

Timepoint

At the beginning of the study, 7 and 14 days after the treatment

Method of measurement

Use the Visual Analogue Scale to measure the itching

Intervention groups

1

Description

Intervention group: After providing the necessary training for parents (mothers) regarding the correct use of Dimethicone lotion, between 10-8 cc of Dimethicone 4% fully covered on all hair of the head, which is slightly dull, rubbed and washed completely after 12-8 hours. Then with the help of a toothed shoulder, all hair parts are fully and at least for 15 minutes was teased and the same treatment is repeated exactly the next week.

Category

Treatment - Drugs

2

Description

Control group: After providing the necessary training for parents (mothers) regarding the correct use of Permetrin shampoo, between 10-8 cc of Permetrin 1% fully covered on all hair of the head, which is slightly dull, rubbed and washed completely after 12-8 hours. Then with the help of a toothed shoulder, all hair parts are fully and at least for 15 minutes was teased and the same treatment is repeated exactly the next week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahar Hospital

Full name of responsible person

Dr. Afsane Sadeghian

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

The personal budget of researchers

Proportion provided by this source

90

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Bagher Sohrabi

Position

Educational Manager of Medical Faculty

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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