

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

Evaluation and comparison of the therapeutic effect of 4% Dimethicone lotion with 4% Eucalyptus sp essential oil on reducing head lice infection in female primary school students in Kerman.

Protocol summary

Study aim

Evaluation and comparison of the therapeutic effect of 4% Dimethicone lotion with 4% Eucalyptus sp essential oil on reducing head lice infection.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3, on 192 students with head lice, R software is used for randomization.

Settings and conduct

randomly selected 20 girls' elementary schools in Kerman city . 96 female students 4% Dimethicone lotion and 96 other students 4% eucalyptus essence lotion for intervention. During days 1, 7, 14, 21, people are examined to check the effect of drugs. This study is double-blind, the patient and the researcher are not aware of the type of treatment. The lotions are coded by the pharmacist, and then the drug codes are returned after the results are determined.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having at least 20 active eggs; females; age 6-12 years; availability during the research. Exclusion criteria: Use of other drugs; Using hair color, hair gel, Henna, and vegetable oils; sensitive to essential oils; no access to them.

Intervention groups

Intervention group 1: 4% Dimethicone lotion.
Intervention group 2: 4% eucalyptus essence lotion.

Main outcome variables

Percentage of contamination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211211053349N2**
Registration date: **2022-09-07, 1401/06/16**

Registration timing: **prospective**

Last update: **2022-09-07, 1401/06/16**

Update count: **0**

Registration date

2022-09-07, 1401/06/16

Registrant information

Name

Leila ShiraniBidabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3132 5053

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2023-03-19, 1401/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the therapeutic effect of 4% Dimethicone lotion with 4% Eucalyptus sp essential oil on reducing head lice infection in female primary school students in Kerman.

Public title

Therapeutic effect of 4% Dimethicone lotion with 4% Eucalyptus sp essential oil on reducing head lice infection.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Female students with head lice Aged between 6-12 years
 Having at least 20 active eggs on visual inspection
Exclusion criteria:
 Using hair color, hair gel; Henna, and vegetable oils
 Having sensitivity to essential oils Use of other drugs
 People who have already used other treatment methods.
 No access to individual

Age
From **6 years** old to **12 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **192**

Randomization (investigator's opinion)
Randomized

Randomization description
 192 female students with head lice lesions participating in the study are randomly assigned to one of two treatment groups. In this study, the block randomization method, blocks of four, is used. Within each block of 4, 2 people are randomly assigned to group A, and two people to group B. 48 blocks of 4 are used to conduct this study. The software used for block allocation is R software. We randomly select created blocks from numbers 1 to 6. Using R software, we choose a random number between numbers 1 and 6. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order. Finally, group A will receive control intervention and group B will receive treatment intervention. Since the study is complete, the data about intervention in each group can be added to the data frame for analysis. The plotblockrand function is used to generate randomization cards to be used when assigning subjects to treatment. Cards are printed and sealed in envelopes, then when a new subject is registered, the next envelope is opened, and the subject is assigned to the appropriate treatment.

Blinding (investigator's opinion)
Double blinded

Blinding description
 This study is double blind, the patient and the treating doctor are not aware of the type of treatment.
 Dimethicone lotion 4% and eucalyptus essential oil 4% are coded by the pharmacist and then the drug codes are returned after the results are determined.

Placebo
Not used

Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Kerman, the beginning of Haft Bagh Alavi axis,
 University of Medical Sciences campus Postal code:
 7616913555 Phone: 034-31325700

City

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Postal code

Postal code: 7616913

Approval date

2022-07-31, 1401/05/09

Ethics committee reference number

IR.KMU.REC.1401.194

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

The percentage of contamination

Timepoint

days1,7,14,28

Method of measurement

Examine

Secondary outcomes

1

Description

Drug resistance

Timepoint

Before starting the intervention, 7, 14 and 21 days after

using the lotion
Method of measurement
Counting adult lice and their eggs

Intervention groups

1

Description

The first intervention group, Dimethicone lotion 4%, the amount of Dimethicone lotion used for each person is 50 ml, the contact time of the lotion with the hair is 8 to 10 hours for Dimethicone lotion, both intervention groups after 1, 7, 14 and 21 days later The use of lotion will be examined in order to check the effect of the drug on reducing and stopping pollution in the school.

Category

Treatment - Drugs

2

Description

Intervention group2: The second intervention group was lotion containing 4% eucalyptus essence, The second intervention procedure is a lotion containing 4% eucalyptus essential oil. The 4% eucalyptus essential oil lotion will be formulated by the pharmacognosy and pharmaceuticals groups of the Faculty of Pharmacy in a volume of one liter and will be divided into 50 ml packages, and each package will be placed in opaque containers on both sides. They will be given the label of how to use and the ingredients inside the package. Both intervention groups will be examined after 1, 7, 14 and 21 days after consuming the lotion in order to check the effect of the drug on reducing and stopping pollution in the school.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Education schools

Full name of responsible person

Dr Leila Shirani-Bidabadi

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lshiranibidabadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr Leila Shirani-Bidabadi

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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

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Dr leila shirani-Bidabadi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Entomology

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Dr Leila Shirani-Bidabadi

Position

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Associate professor

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data analysis

When the data will become available and for how long

2023

To whom data/document is available

Doctors and researchers working in academic institutions

Under which criteria data/document could be used

Only use data analysis

From where data/document is obtainable

Dr Leila Shirani-Bidabadi

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

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Comments