# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Evaluation of the Effect of Topical Herbal Product Based on Olive Oil and Dietary Recommendations Based on Persian Medical Resources in Patients with Resistant Head Lice Treatment

## Protocol summary

**Study aim**

Determining the effect of a topical herbal product based on olive oil containing essential oils of two plants myrtle and oregano and combining it with dietary recommendations in patients with treatment-resistant head lice.

**Design**

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 90 patients. The randomization process was done using the online computerized random allocation sequence and through the dedicated website (https://www.sealedenvelope.com/) of the randomization process.

**Settings and conduct**

The required sample size for each group will be 30 people. After selecting girls' primary schools with a simple random method, students with pediculosis resistant to disease treatment are included in the study. The patients are divided into three groups, the control group is treated with 4% dimethicone lotion twice with an interval of seven days, and the first intervention group takes the medicine three times with an interval of seven days, and the third group receives the medicine and dietary recommendations.

**Participants/Inclusion and exclusion criteria**

Female children with head lice who have not improved with two consecutive courses of treatment; insensitivity to plant essential oils; age 6 to 12 years old; no history of asthma, allergies and skin allergies according to the parents' report; absence of chronic skin disease.

**Intervention groups**

Patients are randomly divided into three groups: the control group receives 4% dimethicone lotion twice with an interval of seven days, the first intervention group receives a topical herbal product three times with an interval of seven days, and the third group receives medication and dietary recommendations. .

**Main outcome variables**

1-The rate of complete recovery based on examination 2-Assessing the severity of pruritus 3-Evaluation of dryness, redness, scaling and irritation to the extent of complications

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20240501061615N1**
Registration date: **2024-08-26, 1403/06/05**
Registration timing: **prospective**

Last update: **2024-08-26, 1403/06/05**
Update count: **0**

**Registration date**

2024-08-26, 1403/06/05

**Registrant information**

**Name**

Afsaneh Mirshahi

**Name of organization / entity**

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Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2024-09-22, 1403/07/01

**Expected recruitment end date**

2025-01-20, 1403/11/01

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Evaluation of the Effect of Topical Herbal Product Based on Olive Oil and Dietary Recommendations Based on Persian Medical Resources in Patients with Resistant Head Lice Treatment

**Public title**
Investigating the effect of an oil product containing essential oils of two plants and oregano on treatment-resistant head lice
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Female children with head lice who have not improved with two consecutive courses of treatment Parents' willingness to cooperate in the plan Insensitivity to plant essential oils Accessibility during research Age 6 to 12 years old No history of asthma, allergies and skin allergies according to the parents' report Absence of chronic skin disease
**Exclusion criteria:**
Allergy history Reluctance to cooperate Allergy to oregano and myrtle
**Age**
From **6 years** old to **12 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **90**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Eligible people are randomly assigned to the groups under study (the herbal product consuming group, the herbal product consuming group with dietary recommendations, and the control group) in a simple random manner and in a ratio of 1:1:1. The randomization process will be done using the online computerized random allocation sequence and through the dedicated website of the randomization process. Allocation of individuals/patients (Randomization) to the groups under study will be hidden for the patient, physician/interventionist, and outcome assessor (allocation concealment). In this way, the belonging of the people to the groups under study is marked on the paper/card and placed inside the opaque envelopes so that its contents cannot be seen from the outside. During the visit of the eligible patient for the study, the attending physician takes one of the envelopes and then opens it, and based on the contents of the envelope, the patient is placed in the intervention 1, intervention 2 or comparison/control group and treatment services are provided.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
Evaluators and analysts will be unaware of the intervention and control groups
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Mashhad University of Medical Sciences
**Street address**
Second floor, Research and Technology Vice-Chancellor, Building number one of Mashhad University of Medical Sciences (Qureshi), in front of Daneshgah 18, Daneshgah St.
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Mashhad
**Province**
Razavi Khorasan
**Postal code**
9138813944
**Approval date**
2024-04-13, 1403/01/25
**Ethics committee reference number**
IR.MUMS.REC.1403.002

## Health conditions studied

### 1

**Description of health condition studied**
Pediculus humanus capitis
**ICD-10 code**
B85.0
**ICD-10 code description**
Pediculosis due to Pediculus humanus capitis Head-louse infestation

## Primary outcomes

### 1

**Description**
The rate of complete recovery based on examination,

visual visit, observation of the intention or adult lice and a questionnaire to determine the severity of the infestation

**Timepoint**

Examinations are generally performed 4 times upon arrival and on days 7, 14 and 21

**Method of measurement**

The rate of complete recovery based on examination, visual visit, observation of the intention or adult lice and a questionnaire to determine the severity of the infestation

## Secondary outcomes

### 1

**Description**

Checking the severity of itching

**Timepoint**

Examinations are generally performed 4 times on arrival and on days 7, 14 and 21.

**Method of measurement**

By completing the questionnaire

### 2

**Description**

Examination of dryness in order to check complications

**Timepoint**

Examinations are generally performed 4 times on arrival and on days 7, 14 and 21.

**Method of measurement**

By completing the questionnaire

### 3

**Description**

Check for redness to check for complications

**Timepoint**

Examinations are generally performed 4 times on arrival and on days 7, 14 and 21.

**Method of measurement**

By completing the questionnaire

### 4

**Description**

Examination of skin irritation in order to investigate complications

**Timepoint**

Examinations are generally performed 4 times on arrival and on days 7, 14 and 21.

**Method of measurement**

By completing the questionnaire

## Intervention groups

### 1

**Description**

Intervention group1:An oily herbal product containing the essential oils of two plants, Myrtus and oregano, will be taken topically three times at intervals of seven days. The hair is completely impregnated with the product and massaged for ten minutes, then covered with a hair cap for 2 hours, and then washed and dried with shampoo, and at the end of each treatment, an examination is done in terms of contamination and its severity.

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group2: In addition to the oily herbal product prescribed in the first group, dietary recommendations based on traditional medicine sources were received in writing, according to the recommendations of Traditional Iranian Medicine, dietary recommendations provided to patients include avoiding the consumption of fast food, sausages, pasta, salads, high-fat foods, figs and berries, salads and yogurt with meals, consumption of liquids with and after meals, eating and Eating beef and veal during the treatment period and the examinations are the same as the first group.

**Category**

Treatment - Drugs

### 3

**Description**

Control group: The control group or the group that is considered as the standard group in this study is the people who will take Dimethicone 4% lotion twice with an interval of seven days. Apply dimethicone lotion to dry hair, from root to tip, then allow it to dry naturally, the lotion should be left on the head for at least 8 hours or overnight, then rinsed thoroughly with water and shampoo.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital (AS) - Iranian and Complementary Medicine Clinic

**Full name of responsible person**

Mirshahi Afsaneh

**Street address**

Iranian and Complementary Medicine Clinic, Imam Reza (AS) Hospital, Ibn Sina St

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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Tafaghodi Mohsen
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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**
Mashhad 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**
Mashhad University of Medical Sciences
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Mirshahi Afsaneh
**Position**
Resident
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## Person responsible for scientific inquiries

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