

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

**Comparison the effectiveness of herbal product of “peganum harmala” and Permethrin1%in treatment of pediculus capitis patient in referrals to health center of Karaj city.**

### Protocol summary

#### Study aim

Comparison of the Effect of Traditional Oils Oil with Shampoo Permethrin 1% on Head Lice Treatment Referring to Karaj Health Center

#### Design

A clinical trial with community based and pragmatic control group, without blindness, is randomized

#### Settings and conduct

Health center of Karaj city

#### Participants/Inclusion and exclusion criteria

Criteria for entering the study 1- Diagnosis of head lice by the expert or doctor of the health center and confirmed by the researcher 2. Satisfaction of the patient or his parents from entering the plan 3. No drug or therapeutic treatment for head lice in the last 4 weeks  
Non-entry criteria 1. Pregnant woman 2- People with skin lesions on the scalp 3. Children under two years old

#### Intervention groups

Esfand oil group; Permethrin shampoo group

#### Main outcome variables

Time to examine symptoms; side effects; reply to treatment; severity of symptoms

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20170825035890N1**  
Registration date: **2018-04-28, 1397/02/08**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

#### Registration date

2018-04-28, 1397/02/08

### Registrant information

#### Name

Mina Maarefvand

#### Name of organization / entity

Iran medical univercity

#### Country

Iran (Islamic Republic of)

#### Phone

+98 26 3460 8945

#### Email address

maarefvand@tak.iums.ac.ir

### Recruitment status

#### Recruitment complete

### Funding source

#### Expected recruitment start date

2018-04-21, 1397/02/01

#### Expected recruitment end date

2018-10-22, 1397/07/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

### Scientific title

Comparison the effectiveness of herbal product of “peganum harmala” and Permethrin1%in treatment of pediculus capitis patient in referrals to health center of Karaj city.

### Public title

Effectiveness of “peganum harmala” in treatment of pediculus capitis

### Purpose

Treatment

### Inclusion/Exclusion criteria

**Inclusion criteria:**

Diagnosis of head lice by an expert or doctor at a health center and approved by a researcher Satisfaction of the patient or his parents from entering the plan No drug or treatment for head lice treatment over the past 4 weeks

**Exclusion criteria:**

Pregnant lady People with skin lesions on the scalp  
Children under two years old

**Age**

From **2 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **86**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done stratified randomization.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

**Street address**

Hafez Street - Behesht Street - Faculty of Traditional Medicine

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-03-18, 1396/12/27

**Ethics committee reference number**

IR.IUMS.REC 1396.9321309006

## 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**

Mature nest, lice egg

**Timepoint**

The first, second, third and eighth day of the onset of treatment

**Method of measurement**

Mature insect count and lice egg

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

In intervention group, two vials each containing 20cc oil esfand is given to be used according to the order. The consumption of oil is such that at the start of treatment 3 days (once a day) and every time the hair and scalp are smeared with oil and rinse after 20 minutes and one week later, the treatment is repeated in the same way.. Both groups emphasize that the drug should be used on dry and clean hair. In both groups, other family members are treated according to the first course of treatment case of family members, the likelihood of reinfection in both groups' decreases. Also, other health care needed to accelerate the treatment process (Including washing, sunbathing, and combing) both groups are trained and stressed to be done. Effect of treatment on the first, second and third days of the onset of the initial dose and one day after the end of the second stage, the treatment was performed with a face examination.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: The other group is given the permethrin shampoo which is used once a day at the start of treatment and once a week later.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Health center of Karaj city

**Full name of responsible person**

Mina Maarefvand

**Street address**

Hafez Street - Behesht Street - Faculty of Traditional  
Medicine

**City**

Tehran

**Province**

Tehran

**Postal code**

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**Phone**

+98 21 86701

**Fax**

+98 21 86701

**Email**

maarefvand@tak.iums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Horiyeh Mohammadi Konari

**Street address**

Hafez Street - Behesht Street - Faculty of Traditional  
Medicine

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**Email**

maarefvand@tak.iums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Mina Maarefvand

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

**Street address**

Hafez Street - Behesht Street - Faculty of Traditional  
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**Email**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Mina Maarefvand

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

Iran University of Medical Sciences

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**Email**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

Original outcome data

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

Since 2020

**To whom data/document is available**

For researchers working in academic and scientific  
institutions and industry professionals

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

No special circumstances

**From where data/document is obtainable**

Email address

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

Receive email, study by researcher within two weeks,  
answering

**Comments**