

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
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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

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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

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

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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