

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation of the efficacy of a formulation of Peganum harmala aqueous extract on patients with head lice

Protocol summary

Study aim

Evaluation of the efficacy of a formulation of Peganum harmala aqueous extract on patients with head lice

Design

Clinical trial without control group and randomization, in phase 2, on 25 patients

Settings and conduct

The clinical trial is conducted in phase 2 on 25 patients in Razi Hospital. After signing the consent form, the quality of life questionnaire is completed by the patients at the beginning and at the end of the treatment. At the end of the treatment, the patients' symptoms are scored based on the Likert scale from 0 to 10. The patient applies the product once a day, each time by smearing all the involved areas and skin of the head and neck, for three consecutive days, and after ten minutes, he washes the head and neck with a softening shampoo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Compliance with head lice diagnostic criteria; age range between 18-65 years; signing the informed consent. Exclusion criteria: Having serious diseases or extensive skin wounds; Allergy to the components of the product; Antibiotic or anthelmintic treatment in the last 1 month

Intervention groups

Intervention group: including 25 people who apply the gel formulation containing Peganum harmala extract on a daily basis for 3 consecutive days

Main outcome variables

Lice affection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160306026938N12**

Registration date: **2022-10-18, 1401/07/26**

Registration timing: **prospective**

Last update: **2022-10-18, 1401/07/26**

Update count: **0**

Registration date

2022-10-18, 1401/07/26

Registrant information

Name

Mahdi Vazirian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-12, 1401/09/21

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of a formulation of Peganum harmala aqueous extract on patients with head lice

Public title

Evaluation of efficacy of Peganum harmala extract on patients with head lice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Conformity with head lice diagnostic criteria
Age range between 18 and 65 years
Signing informed consent
Being in healthy condition
Not using local or systemic anti-lice products during the recent infection

Exclusion criteria:

Local or systemic anti-lice treatment or use of hair dye during or before the study period
Having serious diseases or extensive wounds, especially in the scalp area (such as impetigo or eczema), chronic scalp disorders (such as psoriasis, chronic dermatosis) and secondary scalp infection
Known allergy to any of the components of the product
Treatment with antibiotics (cotrimoxazole, trimethoprim, tetracycline) or anthelmintics (such as ivermectin, levamisole, albendazole) in the last 1 month or other local or systemic drugs that may lead to errors in the test

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of The Institute of Pharmaceutical Sciences- Tehran University Of Medical

Street address

16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219.

City

tehran

Province

Tehran

Postal code

1417613151

Approval date

2022-09-20, 1401/06/29

Ethics committee reference number

IR.TUMS.TIPS.REC.1401.050

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

Lice levels

Timepoint

Before the initiation of intervention and the day after the last application of formulation

Method of measurement

Scoring the patients' symptoms based on a 0-10 Likert Scale with regard to improvements in symptoms (0=no improvement; 10= complete improvement)

Secondary outcomes

1

Description

Quality of life

Timepoint

Before the start of the intervention and one day after the last use of the formulation

Method of measurement

Completion of a 30-question questionnaire on the quality of life of head lice patients by the patient

Intervention groups

1

Description

Intervention group: recipient of gel formulation containing aqueous extract of *Peganum harmala* plus carbomer and sodium hydroxide. In three consecutive days, once a day, the patient smears all the infected areas and the skin of his head and neck with gel and after ten minutes, he washes the stained areas with softening shampoo and water.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Dr. Zeinab Arianian

Street address

Razi hospital, Razi dead end, Vahdat-e-Eslami square, Vahdat-e-Eslami street

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 912 484 8444

Email

razihospital@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Aliakbar Fotohi

Street address

Central organization of Tehran University of Medical Sciences, Corner of Qods street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3639

Email

research@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Room No. 1-206, Second Floor, Old building, Faculty of Pharmacy, 16th Azar Ave., Enqelab Ave.

City

Tehran

Province

Tehran

Postal code

1417614411

Phone

+98 21 6412 1223

Email

Vazirian_m@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mahdi Vazirian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacognosy

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

En Demographic specification of patients, would be published, except their names and address. Primary outcome of the patients would be published, too.

When the data will become available and for how long

En Data would be available 6 months after publishing the results

To whom data/document is available

Data would be available for researchers in academic and scientific organisations

Under which criteria data/document could be used

any type of usage of data is allowable, except using for manufacturing a product.

From where data/document is obtainable

Sending an E. mail to mehdivazirian@gmail.com

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

After receiving E. mail, data would be sent within a week

Comments