

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the efficacy of standard decoction of Peganum harmala seeds on children head lice treatment

Protocol summary

Study aim

Due to the high incidence of head lice in school-age children and reports of lice resistance to existing treatments, in this study, a decoction of peganum harmala seeds was used to treat head lice. The use of this treatment method has been confirmed in traditional Iranian medicine books.

Design

The total sample size is 50 people who are randomly divided into two groups of 25 intervention and control. It should be noted that due to the different packaging of the two products, it is not possible to blind, but the treatment is done randomly so that neither the patient nor the researcher can influence the choice of drug. Also, statistical analysts are unaware of the treatment groups until the end of the study

Settings and conduct

Patients are visited in Baze Sheikh Health Center and the severity of the disease is diagnosed (mild <10, 20> moderate> 10, severe> 20). If there is at least one live lice and its eggs are randomly entered in the intervention and received treatment.

Participants/Inclusion and exclusion criteria

Participants are children in the age range of 3-12 years who have seen at least one live lice and live eggs and have not received treatment in the past week. If the hair length is shorter than 3 cm and also there is an open wound on the head and no referral for follow-up or dissatisfaction to participate in the study will be prevented from entering the study.

Intervention groups

Patients are divided into control and intervention groups who will receive the usual treatment of permethrin as a control group and treatment with peganum harmala decoction as an intervention group.

Main outcome variables

Patients are examined on the first, second, sixth, seventh, and fifteenth days of the study. Evaluation of treatment based on the absence or presence of adult lice

or their eggs as well as its severity will be recorded based on initial observations.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201219049760N1**

Registration date: **2021-07-30, 1400/05/08**

Registration timing: **prospective**

Last update: **2021-07-30, 1400/05/08**

Update count: **0**

Registration date

2021-07-30, 1400/05/08

Registrant information

Name

Motahhreh Bouzari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3876 3372

Email address

bouzarim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the efficacy of standard decoction of
Peganum harmala seeds on children head lice treatment

Public title

Investigation the effect of Peganum harmala decoction
on head lice

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All children between 3-12 years old referred to Baze
Sheikh Health Center with pediculosis diagnose by a
dermatologist: At the study beginning, at least 3 adult
lice or at least 1 adult lice and 10 lice eggs should be
seen in the patient's hair. Obtaining the informed
consent of the patient / parents The patient's hair length
should be at least 3 cm Patient/parents consent of not
using any chemical, plant or other anti - louse treatment
during the study

Exclusion criteria:

Lack of patient/parents consent to participate in study
Failing at follow-up and follow-up visits Children with age
less than 3 years or over 12 Just lice egg are exist in
patient's hair not adult lice Patient's hair cutting below 3
cm length Using from other anti-lice treatment in the last
7 days Taking antibiotics in the last 7 days Open wound
existence in the patient's head Existence of any type of
underlying scalp disease (other than lice) at the study
beginning (such as psoriasis)

AgeFrom **3 years** old to **12 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization method: Block randomization
Randomization tool: <https://www.sealedenvelope.com/>
How to make a random sequence: To perform this
method, the number of intervention groups (two groups
A and B), the volume of each block (6 in each block) and
the number of sample size (90 patients) were entered
into the website. The site then provided a list of 15
blocks, each contains 6 patients. In this study, we use 6
patients in each block and the website randomizes and
numbers the blocks. Allocation Concealment Method:
Sealed Envelopes

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 Mashhad University of Medical
Sciences

Street address

Azadi Square, University Campus, Faculty of
Pharmacy

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2020-11-07, 1399/08/17

Ethics committee reference number

IR.MUMS.REC.1399.487

Health conditions studied**1****Description of health condition studied**

Pediculosis

ICD-10 code

B85.0

ICD-10 code descriptionPediculosis due to *Pediculus humanus capitis***Primary outcomes****1****Description**

Lice eradication rate

Timepoint

Observation of live lice at baseline and on days 2, 6, 7
and 14 after treatment

Method of measurement

By physical examination on specified days

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients will receive standardized pewter spray based on alkaloid Harmine once at the beginning of diagnosis and after one week.

Category

Treatment - Drugs

2

Description

Control group: Patients will receive standard lice treatment using 1% permethrin shampoo once at the beginning of diagnosis and after one week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bazeh Sheykh clinic

Full name of responsible person

Mohaddese Beyki

Street address

No. 35, Poursina Ave, Mashhad, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaqqodi

Street address

Mashhad university of medical science, Azadi Sq.,
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Web page address

<https://www.mums.ac.ir/index.php/en/>

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

Full name of responsible person

Zohreh malekirad

Position

pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Position

Assistant Professor of Pharmacognosy

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

مطهره بوذری

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Ph.D.

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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

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

Title and more details about the data/document

After the study, the results will be published as an article
and all data will be published as supplement.

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

Access starts 6 months after article publication

To whom data/document is available

everybody who have access to the article

Under which criteria data/document could be used

References to study results are permitted.

From where data/document is obtainable

Send email to the corresponding author

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

Documents will be sent 1 to 3 months after sending the
email to the corresponding author.

Comments