

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Efficacy of topical product of Rhus coriaria on head lice

Protocol summary

Study aim

1 - Determine the severity of the contamination with head lice (nit or live lice), before receiving the Rhus coriaria product 2. Determine the severity of the contamination with head lice (nit or live lice), after receiving the Rhus coriaria product 3. Determine rate of head pruritus before receiving the Rhus coriaria product 4 - Determine rate of head pruritus after receiving the Rhus coriaria product 5 - Comparison of the severity of the contamination with head lice (nit or live lice) before and after receiving the Rhus coriaria product 6 - Comparison of the rate of head pruritus before and after receiving the Rhus coriaria product

Design

A clinical trial that has a group and intervention for everyone is the same

Settings and conduct

This is a clinical trial which is carried out at Fardis Health Centers. Patients with head lice and Inclusion criteria entire in the study. Patients only use the drug that they are given. On the 4th, 10th, and 14th days after treatment, Patients are evaluated for lice, nit and degree of itching.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Take at least two continuous period of permethrin, according to the correct instruction and having at least grade one (5-9 nit or live lice) according to severity of the contamination Exclusion criteria :Sensitivity to product, Head skin ulcers, Secondary skin infection including Impetigo and chronic skin disease such as Psoriasis, Immunodeficiency, Pregnancy; Participation in any clinical trial within the past 4 weeks; Use less than twice in every three consecutive days, The concomitant use of another anti-lice drugs

Intervention groups

Group of users of Rhus coriaria product

Main outcome variables

Number of lice, nit and severity of itching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180712040446N1**

Registration date: **2018-07-22, 1397/04/31**

Registration timing: **registered_while_recruiting**

Last update: **2018-07-22, 1397/04/31**

Update count: **0**

Registration date

2018-07-22, 1397/04/31

Registrant information

Name

Atefe Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2247 3630

Email address

atf.sharif@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of topical product of Rhus coriaria on head lice

Public title

Efficacy of topical product of Rhus coriaria on head lice

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Take at least two continuous period of permethrin, according to the correct instruction Having at least grade one (5-9 nit or live lice) according to severity of the contamination

Exclusion criteria:

Sensitivity to product Head skin ulcers Secondary skin infection including Impetigo Chronic skin disease such as Psoriasis Immunodeficiency Pregnancy Participation in any clinical trial within the past 4 weeks Use less than twice in every three consecutive days The concomitant use of another anti-lice drugs

Age

From 2 years old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

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**

Ethics Committee of Shahid Beheshti University of Medical Sciences and Health Services

Street address

No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2017-04-29, 1396/02/09

Ethics committee reference number

IR.SBMU.RETECH.REC.1397.125

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

Pediculosis

ICD-10 code

B85

ICD-10 code description

Head louse infestation

Primary outcomes**1****Description**

Pediculosis severity of contamination

Timepoint

At the beginning of the intervention, 4, 10, and 14 days after the start of the Rhus coriaria product

Method of measurement

Mature insect count and lice egg

Secondary outcomes**1****Description**

Pruritus rate

Timepoint

At the beginning of the intervention, 4, 10, and 14 days after the start of the Rhus coriaria product

Method of measurement

Ask the patient

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

The study will be conducted as a before and after clinical trial . In intervention group, for each patient, 60 cc of Rhus coriaria product, sprayed for three continuous days, 20 cc daily with a plastic brush tiny teeth will be given. The patient should massage each time for 10 minutes on the head and then wrap around a hair a towel and wait for 90 minutes. Then comb with a fine brush. Again 60 cc of the drug is given for use in three continuous days on the seventh, eighth and ninth days. Other family members are treated simultaneously.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Health Center of Fardis city

Full name of responsible person

Atefe Sharif

Street addressCenter for Health Services of Shohadaye
Meshkindasht ,Pasgah Street ,Meshkin Dasht ,Fardis ,
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Email

atf.sharif@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice Chancellor for research,Traditional Medicine
School,Shahid Beheshti University**Full name of responsible person**

Somaye Esmaili

Street addressNo.8 Shams Alley,Opposite Tavarnir Street - Valiasr
St., Tehran**City**

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sesmaeili@sbmu.ac.ir

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

Yes

Title of funding sourceVice Chancellor for research,Traditional Medicine
School,Shahid Beheshti University**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**School of Traditional Medicine, Shahid Beheshti
University of Medical Sciences**Full name of responsible person**

Atefe Sharif

Position

Ph.D Student of Traditional Medicine

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahmouud Khodadost

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Atefe Sharif

Position

Ph.D Student of Traditional Medicine

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because the study is not over.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available