

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Clinical trial to compare efficacy and safety of the Ivermectin 0.5% lotion and Permethrin 1% shampoo for treatment of pediculus humanus capitis infestation.

Protocol summary

Summary

This study aims to determine therapeutic efficacy and safety of the Ivermectin 0.5% topical lotion compared with topical Permethrin 1% in subjects with Pediculus Humanus Capitis infestation. This is a multi central, randomized, double-blind two-arm clinical trial. 88 patients participate in each treatment group. Participants are healthy male and female subjects who are at least 6 months of age and infested with pediculus humanus capitis. Eligible subjects will randomly receive either the Ivermectin 0.5% lotion or topical Permethrin 1% as the treatment and they will be blinded to their type of treatment. Follow-up visits will performed on days 1, 7 and 14 by a trained evaluator. Evaluations will include presence or absence of live lice on the scalp and safety assessments. Primary outcome will be the percentage of patients in both groups with no live lice viable eggs (eggs found within 1.27 cm of the scalp) on the scalp. The secondary outcomes will be observed skin/scalp reactions and ocular irritation assessments.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071320514N5**

Registration date: **2016-10-17, 1395/07/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-10-17, 1395/07/26

Registrant information

Name

Alireza Firooz

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 8897 8190

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Recruitment status

Recruitment complete

Funding source

Gilaranco pharmaceutical and cosmetic company.

Expected recruitment start date

2016-10-22, 1395/08/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to compare efficacy and safety of the Ivermectin 0.5% lotion and Permethrin 1% shampoo for treatment of pediculus humanus capitis infestation.

Public title

Efficacy and safety assessment of the topical Ivermectin 0.5% in pediculus capitis infestation.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: at least 6 months of age; presence of at least 3 live lice or 10 viable eggs (eggs found within 1.27 cm of the scalp); participants with good general health; signing the written informed consent by the

capable participants or by their legal guardians for incapable ones; agree not to use any other forms of lice treatments except the test items; agrees not to cut their hair while participating in the study. Exclusion Criteria: history of irritation or sensitivity to Ivermectin or its components or other pediculicides products; presence of visible skin/scalp condition(s) that are not attributable to head lice infestation, such as an erythema score >2, blisters or vesicles at the treatment site ; presence of eczema or atopic dermatitis at the treatment site; history of treatment for head lice include OTC, home remedy or Rxin during the last 7 days; any condition or illness that, in investigator's opinion, may compromise the objective of the protocol; pregnancy, lactation or planning to become pregnant during the study; participation in a previous investigational drug study within the past 30 days; prior participation in any Ivermectin trials

Age

From **6 months** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **176**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization performed based on block randomization method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Room 105 , 5th floor, Central building of Tehran University of Medical Sciences , Ghods intersection , Keshavarz blvd.

City

Tehran

Postal code

Approval date

2016-04-16, 1395/01/28

Ethics committee reference number

IR.TUMS.REC.1395.2399

Health conditions studied

1

Description of health condition studied

Pediculus Humanus Capitis infestation.

ICD-10 code

B85.0

ICD-10 code description

Pediculosis due to Pediculus humanus capitis

Primary outcomes

1

Description

Percentage of patients in both groups with no live lice or viable eggs (eggs found on hair within 1.27 cm of the scalp) on the scalp examination

Timepoint

Before treatment and 1, 7 and 14 day after treatment

Method of measurement

Physical exam by a trained evaluator

Secondary outcomes

1

Description

Observed skin/scalp reactions and periocular skin irritation

Timepoint

Before treatment and 1, 7 and 14 day after treatment.

Method of measurement

Physical exam by a trained evaluator.

Intervention groups

1

Description

Intervention group: topical Ivermectin lotion, product from Gilaranco company contains Ivermectin 0.5%, once. The whole bottle of the lotion should directly applied on dry hair and scalp and stayed on hair and scalp for 10 minutes after it has been applied. Then the lotion should completely rinsed from hair and scalp using only water.

Category

Treatment - Drugs

2

Description

Control group: Topical Permethrin shampoo, product from Gilaranco company contains 1% Permethrin, twice with one week interval. the whole bottle of the product should be apply on the wet hair and scalp only and stayed on hair and scalp for 10 minutes after it has been

applied. Then it should be rinsed with warm water. The patients should also towel-dry the hair and comb out any tangles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Dr.Maryam Daneshpazhooh

Street address

Vahdat-Eslami Square

City

Tehran

2

Recruitment center

Name of recruitment center

Dr.Zargari skin clinic

Full name of responsible person

Dr.Omid Zargari

Street address

Dana building, Boosar Bridge

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gilaranco pharmaceutical and cosmeceutical company

Full name of responsible person

Najmeh Farahani

Street address

No 6, 4th Floor, Baradaran Shadab Street, North
Iranshahr St

City

Tehran

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

Yes

Title of funding source

Gilaranco pharmaceutical and cosmeceutical company

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Center for Research & Training in Skin Diseases & Leprosy

Full name of responsible person

Alireza Firooz

Position

Dermatologist and professor of Tehran University of Medical Sciences

Other areas of specialty/work**Street address**

No 415, Taleqani avenue.

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Person responsible for scientific inquiries

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Full name of responsible person

Alireza Firooz

Position

Dermatologist and professor of Tehran University of Medical Sciences

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Person responsible for updating data

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Center for Research & Training in Skin Diseases &
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Full name of responsible person

Aniseh Samadi

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General practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty