

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the therapeutic effect of Shirvan herbal ointment with glucantim drug on the cutaneous leishmaniasis wounds.

Protocol summary

Study aim

Determining the therapeutic effect of Shirvan herbal ointment compared to glucantim drug on the cutaneous leishmaniasis wounds.

Design

The clinical trial has a control group, with parallel groups, no blind strain, no randomization, phase 3 on 10 patients.

Settings and conduct

The location of the research is the Skin Disease Research Center of Isfahan University of Medical Sciences. In the case of 10 patients with at least two lesions less than 2 cm, Shirvan herbal ointment (twice a day) for one lesion and glucantim drug (5 ml intralesional injection weekly up to a maximum of 6 times (42 days)) for the other lesion will be used. At each follow-up, the size of erythema, induration, ulceration and scar (the largest diameter times its perpendicular diameter in milliliters) will be recorded. Evaluation of clinical improvement based on complete re-epithelialization of lesions as the main measure of treatment effect, in the last injection session and follow-up period (1, 4 weeks and 6 months) will be performed on each of the treated lesions.

Participants/Inclusion and exclusion criteria

1.Confirmed cases of urban leishmaniasis. 2.Informed consent signed 3.Lesions < 2 cm in diameter, 4.Lesions only in the hands and feet.

Intervention groups

In the case of 10 patients with a minimum lesion of less than 2 cm, Shirvan herbal ointment (twice a day) for one lesion and glucantim drug (intralesional injection of 5 ml weekly up to a maximum of 6 times (42 days)) will be used for the other lesion.

Main outcome variables

Re-epithelialization of lesions, Reducing the average healing time of lesions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230621058552N1**

Registration date: **2023-06-28, 1402/04/07**

Registration timing: **prospective**

Last update: **2026-07-02, 1405/04/11**

Update count: **1**

Registration date

2023-06-28, 1402/04/07

Registrant information

Name

maryam aghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3626 2206

Email address

maryam.aghaei2008@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutic effect of Shirvan herbal ointment with glucantim drug on the cutaneous leishmaniasis wounds.

Public title
Comparison the effect of Shirvan herbal ointment and glucantim drug on the cutaneous leishmaniasis wounds.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed cases of urban leishmaniasis. Informed consent signed The diameter of the lesion < 2 cm. Lesions only in hands and feet.
Exclusion criteria:
Pregnant or lactating women, Cardiovascular patients, Lesions on joints and cartilage, The diameter of the lesions> 2 cm, Illness period of more than 8 weeks, Sperotrichoid and chronic lesions, Using any type of treatment for leishmaniasis in the last month. Participation in any type of project in the last 2 months

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

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 Isfahan University of Medical Sciences

Street address

Hezar Jarib Street . Azadi Square.

City

Isfahan

Province

Isfahan

Postal code

8173963181

Approval date

2023-03-14, 1401/12/23

Ethics committee reference number

IR.ARI.MUI.REC.1401.339

Health conditions studied

1

Description of health condition studied

Leishmaniasis

ICD-10 code

Z68.53

ICD-10 code description

Body mass index (BMI) pediatric, 85th percentile to less than 95th percentile for age

Primary outcomes

1

Description

At each follow-up, the size of erythema, induration, ulceration and scar (largest diameter times its perpendicular diameter in milliliters) will be recorded. Evaluation of clinical recovery based on the complete re-epithelialization of the lesions as the main measure of treatment effect is performed in the last injection session and the follow-up period (1, 4 weeks and 6 months) on each of the treated lesions.

Timepoint

The measurement of the lesion is at the beginning of the study (before the start of the intervention) and 1, 4 weeks and 6 months after the start of taking Shirvan herbal ointment and glucantim medicine.

Method of measurement

The lesion surface will be measured using caliper software.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the case of 10 patients with a minimum lesion of less than 2 cm, Shirvan herbal ointment (twice a day) for one lesion and glucantim drug (intralesional injection of 5 ml weekly up to a maximum of 6 times (42 days)) will be used for the other lesion.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Center for Skin and Skin Diseases

Full name of responsible person

Dr. Seyed Hossein Hejazi

Street address

Sedigheh-Tahereh Hospital. Khoram Street. Jomhori Square.

City

Isfahan

Province

Isfahan

Postal code

81876- 98191

Phone

+98 31 3339 0100

Email

hejazih12@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

Street address

Building No. 4, Research and Technology Vice-Chancellor, Hazar Jarib St.

City

Isfahan

Province

Isfahan

Postal code

81746-73461

Phone

+98 31 3668 7898

Email

research@mui.ac.ir

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Aghaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

Street address

Sedigheh Tahereh Hospital. Khoram Street. Jomhori Square

City

Isfahan

Province

Isfahan

Postal code

81876- 98191

Phone

+98 31 3339 0100

Email

maryam.aghaei2008@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Zabih Allah Shahmoradi

Position

Director of the Research Center for Skin Diseases and Salk

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Sedighe And Tahereh Clinic. Khoram Street, Jomhoori Square ,

City

Isfahan

Province

Isfahan

Postal code

81876- 98191

Phone

+98 31 3339 0100

Email

emrc@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Aghaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

Street address

Sedighe And Tahereh Clinic, Khoram Street, Jomhori Square

City

Isfahan

Province

Isfahan

Postal code

81876- 98191

Phone

+98 31 3339 0100

Email

maryam.aghaei2008@gmail.com

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

There is no further information

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

Undecided - It is not yet known if there will be 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

Trial results

Please tick if results have been published

Yes

Summary result posting date

2026-07-02, 1405/04/11

Table of baseline comparison

	Test(n=30)	Control(n=30)	P
Age (years)	26.9±13.3	33.16±12.80	0.07
Mean number of lesions (±SD)	1.8±1.1	2.1±1.1	0.265
Mean duration of treatment (day)	30.5±7.4	43.9±14.4	0.00
Mean lesion location (upper limbs)	0.9±0.92	0.8±0.84	0.66

Participant flow diagram

Table of variable outcomes' results

Week	Test (n=30)	Control (n=30)	P
Before treatment	50.8±31.2	51.5±32.5	0.93
First week	40.9±26.4	45.9±31.1	0.5
Second week	30.1±21.4	40.1±29.2	0.139
Third week	19.3±18.0	31.3±25.8	0.04
Fourth week	9.2±11.7	23.6±22.4	0.003
Fifth week	3.8±6.9	17.6±19.6	0.001
Sixth week	0.92±2.3	12.6±15.7	0.00
Seventh week	0.00±0.00	11.5±16.1	0.00
Eighth week	0.00±0.00	11.1±16.2	0.00

Table of adverse events

First publication date

2024-08-26, 1403/06/05

Abstract of published paper

Background: Cutaneous leishmaniasis (CL) infection is caused by the Leishmania major (L. major) parasite and affects 1.5 to 2 million people worldwide each year. Although research into vaccines and antiparasitic drugs has been somewhat successful, their adverse effects include high toxicity, prolonged regeneration, and scarring. This has highlighted the importance of research to replace natural products with antibacterial and antioxidant properties, such as vegetable

extracts and oils. Since, the anti-leishmaniasis effect of each of the components of Shirvan herbal ointment (aloe vera, Brazembel, *Nigella sativa*, propolis, lavender, and olive oil) has been separately studied and confirmed, it seems that the combination of these components can have an increasing anti-leishmanial effect to treat CL. Therefore, this study investigated the therapeutic impact of Shirvan herbal ointment on Iranian patients with leishmaniasis in comparison with glucantime (meglumine). Materials and Methods: Sixty patients with leishmaniasis were divided into the control and test groups. The control and test groups received intralesional glucantime and Shirvan herbal cream (two times daily), respectively. Results: The size mean of the lesion was 51.5 ± 32.5 before and 11.11 ± 16.28 after treatment in the control group and 50.8 ± 31.2 before and 0.0 ± 0.0 after treatment in the test group. In addition, the period mean of treatment was 43.9 ± 14.4 days and 30.5 ± 7.4 days in the control and test groups, respectively. There was a significant difference in lesion size between the two groups after treatment. Conclusion: Data suggested that Shirvan herbal ointment can be an alternative drug in the treatment of human CL.