

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparing the effect of Herbal paste mainly made of Lowsonia inermis, Zataria multiflora and opium, to Glucantime in the treatment of patients with cutaneous Leishmaniasis.

Protocol summary

Study aim

Comparing the effect of Herbal paste mainly made of Lowsonia inermis, Zataria multiflora and opium, to Glucantime in the treatment of patients with cutaneous Leishmaniasis.

Design

Patients are divided into 50 persons on the basis of the date of entry. Patients are unaware of the treatment and they will be treated in two separate centers.

Settings and conduct

Study will be done in Fars Province, which is an endemic area of cutaneous leishmaniasis. It will be done in two centers of the city of Shiraz and Karamah and Coordinated with the health department.

Participants/Inclusion and exclusion criteria

Confirmation of CL based on positive smear culture positive from lesion PCR positive less than 70 years not getting any medication. Exclusion: Pregnant women Mother feeding their babies Using immunodeficient drugs from three months ago using any treatment for leishmaniasis

Intervention groups

They will be divided into two groups: The first group (control), will be treated with glucantime according to the standard, The second group (intervention), will be treated with the topical herbal paste of Lowsonia inermis and Zataria multiflora for the same duration.

Main outcome variables

Decreased inflammation, shrinkage of the wound, absence of parasite in the wound

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150105020570N3**

Registration date: **2018-06-18, 1397/03/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-18, 1397/03/28**

Update count: **0**

Registration date

2018-06-18, 1397/03/28

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5291

Email address

motazedm@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-10, 1397/02/20

Expected recruitment end date

2018-09-16, 1397/06/25

Actual recruitment start date

2018-05-10, 1397/02/20

Actual recruitment end date

2018-09-16, 1397/06/25

Trial completion date

empty

Scientific title

Comparing the effect of Herbal paste mainly made of Lowsonia inermis, Zataria multiflora and opium, to Glucantime in the treatment of patients with cutaneous Leishmaniasis.

Public title

Evaluation of Lowsonia inermis (Henna) and Zataria multiflora (Shirazi thyme) in treatment of cutaneous leishmaniasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 confirmation of CL based on positive smear culture
 positive from lesion PCR positive Under 70 years old
Exclusion criteria:
 pregnant women mother feeding their babies using immunodeficient drugs from three months ago using any treatment for leishmaniasis

Age
To 70 years old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
 Target sample size: 120
 Actual sample size reached: 100

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be divided in two A and B groups according to their alphabetic names.

Blinding (investigator's opinion)
Double blinded

Blinding description
1.individuals who received the treatment. 2.analyzer of data who examine the patients after three months and evaluate the results.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Shiraz University of Medial Sciences
Street address
 Shiraz Blv Zand
City
 Shiraz-
Province
 Fars

Postal code
7134845794

Approval date
2015-07-23, 1394/05/01

Ethics committee reference number
IR.SUMS.REC.1394,79

Health conditions studied

1

Description of health condition studied
Cutaneous leishmaniasis

ICD-10 code
B55.1

ICD-10 code description
Cutaneous leishmaniasis

Primary outcomes

1

Description
Decreased inflammation, shrinkage of the wound, absence of parasite in the wound

Timepoint
14 days,45days ,3 month

Method of measurement
Observation and measure of the lesion

Secondary outcomes

1

Description
Pour the ointment prepared from the mixture of henna and Shirazy thyme once a day for 14 days.

Timepoint

Method of measurement

Intervention groups

1

Description
Pour the ointment prepared from the mixture of henna and Shirazy thyme once a day for 14 days.

Category
N/A

2

Description
Control group: This group receives the glucantime drug used in the treatment of the disease in standard form

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
kharameh Health and tretment Center

Full name of responsible person
Moghadami Mohsen

Street address
Shiraz Zand Blv

City
Shiraz- kharameh

Province
Fars

Postal code
7134845794

Phone
+98 71 3230 5291

Fax
+98 71 3230 5291

Email
motazedm@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences, Shiraz, Iran.

Full name of responsible person
Basir Hashemi

Street address
Vice Chancellor of Research Shiraz University of Medical Sciences, Shiraz, Iran

City
Shiraz Kharameh

Province
Fars

Postal code
7134845794

Phone
+98 71 3212 2389

Email
motazedm@sums.ac.ir

Grant name

Grant code / Reference number
94-7547

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source

Shiraz University of Medical Sciences, Shiraz, Iran.

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
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Hossein Motazedian

Position
PhD of Parasitology , Mycology

Latest degree
Ph.D.

Other areas of specialty/work
Parasitology

Street address
School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran.

City
Shiraz

Province
Fars

Postal code
7134845794

Phone
+98 71 3230 5291

Fax

Email
motazedm@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mohammad Hossein Motazedian

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Parasitology

Street address
Shiraz University of Medical Sciences Zand Blv

City
Shiraz

Province
Fars

Postal code
7134845794

Phone
+98 71 3230 5291

Fax

Email
motazedm@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad Hossein Motazedian

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Parasitology

Street address

Zand Blv

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 3230 5291

Email

motazedm@sums.ac.ir

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

Yes - There is a plan to make this available

Title and more details about the data/document

The total potential data can be shared after
unidentifiable people

When the data will become available and for how long

After registering the drug and printing the article.

To whom data/document is available

Only for researchers working in academic and scientific
institutions.

Under which criteria data/document could be used

Analyzed data is available.

From where data/document is obtainable

Refer to the author for reference.

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

After the article is published.

Comments