

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the effect of herbal medicine prepared from Oak in human phase in patients with cutaneous leishmaniasis.

Protocol summary

Study aim

Utilization of an effective and low-risk herbal ointment for cutaneous leishmaniasis treatment.

Design

Sampling method: simple and accessible Sample size: 60 patients In data analysis, first, the normality of the data was examined using a one-sample Kolmogorov-Smirnov test with Lili-Fars modification. By confirming the normality, appropriate parametric methods such as the student test were used, and if not normal. Mann-Whitney and Wilcoxon tests are used. In analyzing data with nominal scale, Chi-square test is used and in cases where more than 20% of the expected frequencies of tables are less than 5 (Cochran), Fisher's exact test is used. Analysis of covariance will be used to evaluate the results. The software used in this study is IBM-SPSS v.25 and the significance level of the tests is less than 5%.

Settings and conduct

Study type: Clinical trial Location: Sima Teb Clinic and Innovation Research Center of Shahinfar Medical School - Islamic Azad University of Mashhad.

Participants/Inclusion and exclusion criteria

Admission: Patients with active leishmaniasis ulcers on their skin for less than 4 months. No entry: People with inactive leishmaniasis ulcers on their skin.

Intervention groups

30 patients who diagnosed with leishmaniasis and took sampling for the spread of suspicious skin lesions before and after treatments with pathologist approval. This group receives selective treatment for leishmaniasis (as confirmed by a dermatologist including paromomycin, fluconazole, or pentamidine) and the herbal medicine of Oak at the same time. Nevertheless, The control group of other 30 patients with leishmaniasis ulcers, receives only selective treatment for leishmaniasis.

Main outcome variables

Herbal ointment Age Gender Interleukin-4 Interleukin-2 Interleukin-10 Interferon Gamma Beta tumor growth factor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201226049841N1**

Registration date: **2021-01-26, 1399/11/07**

Registration timing: **prospective**

Last update: **2021-01-26, 1399/11/07**

Update count: **0**

Registration date

2021-01-26, 1399/11/07

Registrant information

Name

Mohammad Reza Khakzad

Name of organization / entity

Islamic Azad University, Mashhad, Iran

Country

Iran (Islamic Republic of)

Phone

+98 51 3225 6291

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mr.khakzad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-03, 1399/11/15

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of herbal medicine prepared from Oak in human phase in patients with cutaneous leishmaniasis.

Public title

Evaluation of the effect of Oak powder for the treatment of leishmaniasis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with active leishmaniasis ulcers on a part of their body. Patients with less than 4 months of leishmaniasis develops on their skin.

Exclusion criteria:

Patients with inactive leishmaniasis on their skin. Any drug allergy recognition by medical practitioner.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

volunteer participants will only keep blind in this trial.

Placebo

Not used

Assignment

Other

Other design features

In the following research, 60 leishmaniasis positive cases are going to be examined by a dermatologist and in case of confirmation, they will be divided into 2 groups. First group including 30 patients prescribed with topical cream made of Oak extract in combination with Sina Emfolish topical ointment or at the discretion of the physician with additional glucantime. The second group receive common treatments for leishmaniasis as of topical ointment of Sina Emfolish, and at the discretion with additional glucantime. Procedure started by taking smear from wounded skin area for direct and molecular smear tests. Then treatments continue with twice daily usage of topical ointment. After two months, once again smear will be taken from wounded area. Meanwhile dermatologist survey clinical status of the wound and report every case condition. Second group treatment duration is in accordance with remedy protocols and dermatologist discretion.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Biomedical Research - Islamic Azad University, Mashhad Branch

Street address

Faculty of Medicine, Azad University of Mashhad, 14th Imam Khomeini St., 14th Imam Khomeini St., Imam Khomeini Blvd., Mashhad, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9133683633

Approval date

2020-08-05, 1399/05/15

Ethics committee reference number

IR.IAU.MSHD.REC.1399.091

Health conditions studied

1

Description of health condition studied

Leishmaniasis

ICD-10 code

B55

ICD-10 code description

Leishmaniasis

Primary outcomes

1

Description

wounds larger than ≥ 3 cm

Timepoint

Before treatments begin and 8 weeks after it

Method of measurement

Direct blood smear and PCR test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: cases under treatment with Oak ointment. Ingredients: Oak ointment, Density of 8g in 100 dosage of use. Consumption: Once a day with refreshing bondage. Number of usage: 20 times. Period:

20 days. Method: Topical. Manufacturer: Zojaj Daru

Category

Treatment - Drugs

2

Description

Control group: group treated with common drug.
Consumption: Glucantime ampoule or Sina ampoule ointment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sima Teb Clinic

Full name of responsible person

Vahid Sepehr

Street address

No. 96, Kolahdooz Boulevard 8th, Kolahdooz Blvd.

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Email

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Web page address

<http://www.simateb.com>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Marham Sazan Moghan Daroo Company

Full name of responsible person

Majid Zowghi Kakhki

Street address

Unit 3, 20th floor, Alton Tower, Daneshgah Street

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Province

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9138833114

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+98 51 3129 1704

Email

m.zowghi@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Marham Sazan Moghan Daroo Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Sima Teb Clinic

Full name of responsible person

Vahid Sepehr

Position

Dermatologist

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Web page address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Medicine, Islamic Azad University, Mashhad Branch

Full name of responsible person

Mohammad Reza Khakzad

Position

Director of Medical Innovation Research Center

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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

Faculty of Medicine, Islamic Azad University, Mashhad Branch

Full name of responsible person

Mohammad Reza Khakzad

Position

Director of Medical Innovation Center

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Yes - There is 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

Undecided - It is not yet known if there will be 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

Consent form; - This form is in accordance with the information related to the research and prepared in non-specialized and understandable literature for sixth grade graduates. - Simple and fluent sentences are used to make forms comprehension easier. - Each paragraph provided with more explanations in the form of comments for better adjustment and understanding. - In case of underage participation, it has been stated that the participant is a child or a person who does not have the authority to decide, and the cases where the meaning of "I" was the participant has been changed to "child" or "the person under my care". Also in items where "I" refers to the person approval, it changed to "guardian" or "legal guardian".

When the data will become available and for how long

6 months

To whom data/document is available

Researchers

Under which criteria data/document could be used

Only wound macroscopic results

From where data/document is obtainable

Research Supervisor: Dr. Mohammad Reza Khakzad - Faculty of Medicine, Azad University of Mashhad

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

Contact via email with Dr. Mohammad Reza Khakzad at: mr.khakzad@gmail.com

Comments

According to the ethical documentation of the project, the information of this research will remain confidential with the treating physicians and will be sent only through the person in charge of the research to researchers who intend to improve the treatment of patients.