

# 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

##### Email address

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  $\geq 3$  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.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9183837341

**Phone**

+98 51 3845 9666

**Fax**

+98 51 3846 2869

**Email**

info@simateb.com

**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

**City**

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**Province**

Razavi Khorasan

**Postal code**

9138833114

**Phone**

+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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**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

**Street address**

Shahin Far College, Imam Khomeini 14th, Imam Khomeini Blvd.

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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**

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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.