

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of the treatment of cutaneous leishmaniasis with thymol loaded chitosan gel, as topical supplemental therapy (A RCT study)

Protocol summary

Study aim

Evaluation of cutaneous leishmaniasis treatment with thymol compared with the standard group.

Design

Six groups included chitosan gel (2% and 4%) alone, and chitosan gel containing 5, 10, and 15% thymol compared to standard treatment (glucantime (routine patient therapy)).

Settings and conduct

All patients with at least two wounds who refer to Health Center No. 1 in Mashhad for treatment for the first time

Participants/Inclusion and exclusion criteria

Inclusion criteria There are at least two lesions in the skin, in one case intervention + glucantime and in the other lesion only glucantime is prescribed. Age from 15 to 60 years. Skin lesions at least one centimeter in size. Leishmaniasis confirmed by a parasitologist. Signature of consent form. Exclusion criteria Pregnant women and children under 15 years. Existence of multiple lesions and severe deterioration of the disease. Having diabetes. Any medication used to treat leishmaniasis Drug addiction and smoking. Taking immunosuppressive drugs. Having scars of leishmaniasis on the face

Intervention groups

First, a wound will be treated with a two-percent chitosan gel Second, a wound will be treated with a 5% chitosan gel Third: A wound will be treated with a treatment base, ie Kitozan gel with the best-determined concentration, along with 5% thymol. Fourth: A wound will be treated with a treatment base, ie Kitozan gel with the best-determined concentration along with ten percent thymol. Fifth: A wound will be treated with a treatment base, ie Kitozan gel with the best-determined concentration, along with 15% thymol.

Main outcome variables

Twice a week, the lesions is examined by a dermatologist with some index of wound healing. Every three days to 45 days, the final assessment is performed by the research team.

General information

Reason for update

Acronym

cutaneous leishmaniasis

IRCT registration information

IRCT registration number: **IRCT20180526039848N1**

Registration date: **2020-07-12, 1399/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-12, 1399/04/22**

Update count: **0**

Registration date

2020-07-12, 1399/04/22

Registrant information

Name

Elham Moghaddase

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3884 9410

Email address

moghaddase@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2021-03-10, 1399/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the treatment of cutaneous leishmaniasis with thymol loaded chitosan gel, as topical supplemental therapy (A RCT study)

Public title

Treatment of cutaneous leishmaniasis with thymol loaded chitosan gel

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

There are at least two lesions, in one case intervention + glucantime and in the other lesion only glucantime is prescribed. 15 to 60 years Skin lesions at least one centimeter in size Leishmaniasis confirmed by a parasitologist consent signature

Exclusion criteria:

People who do not use the drug according to the plan
People who do not go to the clinic on the scheduled days

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Those who evaluate the outcome are different from those who give the drug to the patient (the doctor gives the medicine) and the consequences will only be written by the code on a separate sheet (the consequences by the code introduced by the student). The statistician does not know any of the groups and does not know the type of treatment and will only do statistical work with specific codes.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

13131 - 99137

Approval date

2019-02-05, 1397/11/16

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1398.224

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**

Measuring the lesion diameter (millimeters) using image processing software

Timepoint

From the first week of treatment and patient visit the clinic for the first time (once every three days to 45 days)

Method of measurement

processing software

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group 1: Includes ten people with 2% chitosan gel in one of the wounds plus glucantime to increase the effectiveness compared to the other wound of the patient who is treated only with glucantime.

Category

Treatment - Drugs

2**Description**

Intervention Group 2: Includes ten people with 5% chitosan gel in one of the wounds plus Glucantime to

increase the effect compared to the other wound of the patient who is treated only with Glucantime.

Category

Treatment - Drugs

3

Description

Intervention Group 3: Includes ten individuals with the appropriate percentage of chitosan gel from the two primary intervention groups in combination with 5% thymol in one of the wounds locally plus glucantime to increase the effective effect compared to the patient's other wound only It is treated with glucantime, it is done

Category

Treatment - Drugs

4

Description

Intervention Group 4: Includes ten individuals with the appropriate percentage of chitosan gel from the two primary intervention groups in combination with 10% thymol in one of the wounds locally plus glucantime to increase the effective effect compared to the patient's other wound only It is treated with glucantime, it is done

Category

Treatment - Drugs

5

Description

Intervention Group 5: Includes ten individuals with the appropriate percentage of chitosan gel from the two primary intervention groups in combination with 15% thymol in one of the wounds locally plus glucantime to increase the effective effect compared to the patient's other wound only It is treated with glucantime, it is done

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Haft Tir BLV - Villa Street

Full name of responsible person

Dr. razieh hoseini

Street address

Haft Tir BLV - Villa Street

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9179793945

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HoseiniFR@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Bibi Razieh Hosseini Farash

Street address

Mashhad.Medical faculty. Parasitology department

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HoseiniFR@mums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Bibi Razieh Hosseini Farash

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Parasitology

Street address

Department of Parasitology and Mycology, Faculty of Medicine, Mashhad University

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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HoseiniFR@mums.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

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

All images of patients' wounds during treatment

When the data will become available and for how long

Up to two years after the completion of the project

To whom data/document is available

Project collaborators

Under which criteria data/document could be used

Have a face-to-face conversation with project executives about your idea

From where data/document is obtainable

Have a written request or in person with the project executors

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

A written request should be given to the executors of the project

Comments