Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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+98 51 3884 9410

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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 aquare
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

City

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9179793945

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Email

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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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

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

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Person responsible for scientific inquiries

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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