Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effectiveness of topical gel treatment containing standardized 5% hydroalcoholic extract of Zataria multiflora in comparison with intra lesional(IL) glucantime in the treatment of cutaneous leishmaniasis in human

Protocol summary

Study aim
effectiveness of gel 5% of Zataria multiflora with topical Glucantime.

Design
1- Treatment with topical thyme gel 0.5 g for 2 times a day with topical injection of Glucantime once a week for 8 weeks until complete wound healing. Topical injection of Glucantime every week for 8 weeks with placebo (gel base) twice a day. Type of study is Randomized, double-blind, placebo controlled clinical trial. several patients are determined by patch test (80). (Randomized Allocation) are assigned to one of two treatment groups. In the research center, 40 patient lesions are treated topically with Glucantime injection with placebo gel and 40 patient lesions are treated topically with 5% thyme gel and topical Glucantime injection. Clinical trial is 3 phase.

Settings and conduct
40 patient lesions are treated with glucantime with placebo gel and 40 patient lesions are treated topically with 5% thyme gel and topical injection of glucantime. This is a double-blind study. The patient and the treating physician are not aware of the type of treatment. The topical gels are coded by the pharmacist and then the drug codes are returned after the results are known. Thyme gel and placebo gel are made by a pharmaceutical company.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with cutaneous leishmaniasis.5 years old or older. both sexes. wounds should not be more than 5.There should be no sores on the face or ears. positive smear test. exclusion criteria : Patients have not been treated. Pregnant and lactating women. severely susceptible to Glucantime

Intervention groups
1- Treatment with topical thyme gel at the rate of 0.5 g at a rate of 2 times a day with topical injection of Glucantime once a week for 8 weeks Topical injection of Glucantime every week for 8 weeks with placebo (gel base) twice a day.

Main outcome variables
healing ,lesion diameter, Recurrence

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211211053349N1**
Registration date: **2022-03-25, 1401/01/05**
Registration timing: **retrospective**

Last update: **2022-03-25, 1401/01/05**
Update count: **0**

Registration date
2022-03-25, 1401/01/05

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2021-12-25, 1400/10/04

Expected recruitment end date

2022-02-18, 1400/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of topical gel treatment containing standardized 5% hydroalcoholic extract of Zataria multiflora in comparison with intra lesional(IL) glucantime in the treatment of cutaneous leishmaniasis in human

Public title

Evaluation of leishmaniasis wound healing in topical treatment with 5% thyme gel versus intra lesional(IL) Glucantime treatment

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Patients must be 5 years old or older. The patient can be of both sexes. The number of wounds should not be more than 5. No sores on the face or ears. Affirmation of parasitic infection is required The patient has cutaneous leishmaniasis. The onset of their disease is less than 4 months

Exclusion criteria:

Pregnant women are excluded from the study. Patients with severe hypoglycemia are excluded from the study. Breastfeeding women are excluded from the study. Patients who have been treated with other methods (systemic Glucantime, combination therapy, etc.) patients who have been treated in other clinical trial

Age

From **5 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

80 lesions of patients with rural cutaneous leishmaniasis (leishmaniasis) participating in the study are randomly assigned to one of two treatment groups. In this study, block randomization method is used, for which block is used. Fours are used. Regarding the details of how to do randomization, in block randomization the size of all blocks is equal. Within each block of 4, 2 people are randomly assigned to group A and 2 people are randomly assigned to group B. 20 blocks of 4 are used for this study. Be. Block randomization is to ensure that exactly the same number of participants enter the intervention and control group at consecutive but equal intervals. The size of each block is 4 people. In this way, for example, one type of treatment is given to the first block, another type to the second, and again the first type to the third block, and so on. The advantage of block randomization is that the balance of the number of participants in each group is guaranteed. The difference in the number of people in each group will never be more than half the number of people in each block. Performing design of blocked randomization experiments with R software, which is one of the best statistical software. This software uses Package Blockrand. This package creates a random block for clinical trials and helps create randomization cards that the study coordinator can use to assign new people to his or her treatment. Random Block Quadruple All possible blocks are arranged as follows Block 1: ABAB block 2: AABB block: 3: ABBA block 4: BBAA block 5: BABA Block 6: BAAB We need 20 blocks to select 80 people. We randomly select these blocks from 1 to 6. Using software R, we choose a random number between the numbers 1 to 6. For example, if the number 6 Selected as the first block and number 2 as the second block, BAABAABB will be given to the participants in the study, respectively. Finally, group A will receive control intervention and group B will receive treatment intervention. The blockrand function is used to create a data frame with sequential block treatment randomizations. When performing a categorized study, you must run blockrand once for each layer, then optionally combine different data frames with rbind. Save the data frame (s), and when the study is complete, the data can be added to the data frame for analysis. The plotblockrand function is used to create randomization cards to be used when assigning people to treatment. The cards are printed and sealed in envelopes, then when a new subject is registered, the next envelope is opened and the subject is assigned to the relevant treatment. This function generates random allocation for clinical trials. Randomization is done in blocks to balance the treatments.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study. The patient and the treating physician are not aware of the type of treatment. The topical gels are coded by the pharmacist and then the drug codes are returned after the results are known. Thyme gel and placebo gel are made by a pharmaceutical company.

Placebo

Used

Assignment

Parallel

Other design features

Type of double-blind randomized clinical trial studyRandomized, double-blind, placebo controlled clinical trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

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Approval date
2021-12-06, 1400/09/15

Ethics committee reference number
IR.KMU.REC.1400.536

Health conditions studied

1

Description of health condition studied
lesion of cutaneous Leishmaniasis

ICD-10 code
B55.1

ICD-10 code description
Cutaneous leishmaniasis

Primary outcomes

1

Description
wound healing

Timepoint
lesion diameter

Method of measurement
recurence

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Topical thyme gel treatment 0.5 gram for 2 times a day with topical injection of Glucantime once a week for 8 weeks until complete wound healing.

Category
Treatment - Drugs

2

Description
Control group: Topical injection of Glucantime every week for 8 weeks with placebo (gel base) 2 times a day.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Davari center

Full name of responsible person
Leila Shirani

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Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

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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
Kerman 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

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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

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

Some of the patient data recorded in the questionnaire can be shared.

When the data will become available and for how long

Access starts from March 1401

To whom data/document is available

Researchers and physicians working in private and public research and treatment centers

Under which criteria data/document could be used

Doctors, specialists and researchers who treat leishmaniasis patients in medical and research centers are allowed to send requests for unidentifiable personal data or other documents. No analysis is allowed on the delivered data.

From where data/document is obtainable

Dr leila Shirani Bidabadi Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran Postal Code: 7616913555 Phone : 009834 31325829 Fax : 009834 31325830 Mobile :09132196482

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

Due to the fact that patients with leishmaniasis ulcers come in the period of autumn and winter. Until the fall of 1402, these documents are available.

Comments

After justifying the goals of the project and before any treatment, consent is obtained from the patient