

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Comparative assessment of topical Glucantime® injection plus cryotherapy, and cryotherapy alone for Treatment of Anthroponotic cutaneous leishmaniasis

Protocol summary

Study aim

A Comparative assessment of topical Glucantime® injection plus cryotherapy, and cryotherapy alone for Treatment of Anthroponotic cutaneous leishmaniasis

Design

Two arm parallel group randomised trial with blinded postoperative care. Out of 476 patients , 276 in the cryotherapy group plus glucantime injection, and 200 in the cryotherapy group alone. The rand function method in Excel software was used for randomization.

Settings and conduct

In the cryotherapy group, the liquid nitrogen from the nitrogen tank is placed around the lesion for 15 to 20 seconds with the help of cotton swabs for a week and the whole area of the lesion is treated in this way. In the cryotherapy and glucantime injections group, in addition to cryotherapy, glucantime ampoules are injected simultaneously into the lesion caused by the disease with an insulin syringe at an angle of 180 degrees. The rand function method in Excel software was used for randomization.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over one year, onset of disease in less than 4 weeks, Exclusion criteria: use of antibiotics or other antimicrobial drugs for leishmaniasis in the past 4 weeks, extensive lesions with a diameter of more than 5 cm and more than 3 lesions on the patient's body.

Intervention groups

Of the 476 patients examined, 276 in the cryotherapy plus Glucantime® injections group and 200 were included in the cryotherapy alone group

Main outcome variables

Diameter size of cutaneous leishmaniasis lesions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170723035248N4**

Registration date: **2020-10-09, 1399/07/18**

Registration timing: **retrospective**

Last update: **2020-10-09, 1399/07/18**

Update count: **0**

Registration date

2020-10-09, 1399/07/18

Registrant information

Name

Abedin Saghafipour

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25 3784 2228

Email address

asaghafi@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2020-03-18, 1398/12/28

Actual recruitment start date

2013-03-20, 1391/12/30

Actual recruitment end date

2020-03-18, 1398/12/28

Trial completion date

2020-03-18, 1398/12/28

Scientific title

A Comparative assessment of topical Glucantime® injection plus cryotherapy, and cryotherapy alone for Treatment of Anthroponotic cutaneous leishmaniasis

Public title

Comparison of the efficacy of glucantime and cryotherapy simultaneously and cryotherapy alone in the treatment of cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Criteria for joining the study include age over one year Onset of disease in less than 4 weeks.

Exclusion criteria:

Criteria for withdrawing from the study include use of antibiotics or other antimicrobial drugs for leishmaniasis in the past 4 weeks Extensive lesions with a diameter of more than 5 cm and more than 3 lesions on the patient's body.

Age

From **1 year** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **476**

Actual sample size reached: **476**

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, block randomization method will be used for random allocation. The blocks size will be 4 and for this purpose, 25 blocks with 4 subjects in each block will be used. the combination of all patterns will be considered including AABB, ABAB, BABA, BBAA, BABA, BAAB. For selecting each blocks, Dice dropped and the bloc number will be selected. this procedure continued to completed the allocation and reached to sample size.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qom University of medical

Sciences, Bam, Iran

Street address

Safa Shahr street, Jihad Daneshgahi street., alley 4,

City

Qom

Province

Ghous

Postal code

3711675549

Approval date

2020-09-15, 1399/06/25

Ethics committee reference number

IR.MUQ.REC.1398.105

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

En measuring surface of healed tissue of people with cutaneous leishmaniasis

Timepoint

Six weeks after the last treatment in both groups, skin lesions are assessed.

Method of measurement

Calibrated ruler

Secondary outcomes

1

Description

Elimination of inflammatory symptoms and tissue hardness and healing of papules and ulcers are considered as complete recovery.

Timepoint

Six weeks after the last treatment

Method of measurement

Calibrated ruler

Intervention groups

1

Description

cryotherapy simultaneously with intralesional injection of Glucantime®

Category

Treatment - Drugs

2

Description

Intervention group: cryotherapy alone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of Qom

Full name of responsible person

Abedin Saghafipour

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Pardisan, Behesht Blvd., Mellat St., No. 17

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Abedin Saghafipour

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Qom - Pardisan - Behesht Boulevard - Mellat Street - Alley 4

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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

Ghous 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

Ghous University of Medical Sciences

Full name of responsible person

Abedin Saghafipour

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Entomology

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Person responsible for updating data

Contact

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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

Medical records

When the data will become available and for how long

Access period starts one month after the results are published.

To whom data/document is available

public

Under which criteria data/document could be used

Unconditional.

From where data/document is obtainable

Abedin Saghafipour - Faculty of Health, Qom University of Medical Sciences, Qom, Ruhollah Square, next to the Blood Transfusion Organization, Faculty of Health, Room 16 Phone: 09124397413 Email address: abed.saghafi@yahoo.com

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

Unconditional.

Comments