Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 25 3784 2228

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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, Ḍice drooped 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, Jahad Daneshgahi street., alley 4,
City
Qom
Province
Ghoum
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
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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Abedin Saghafipour
Position
Assisstant professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Entomology
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Person responsible for updating data

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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