

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 Saghaipour

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		Sciences, Bam, Iran		
Public title	Comparison of the efficacy of glucantime and cryotherapy simultaneously and cryotherapy alone in the treatment of cutaneous leishmaniasis	Street address	Safa Shahr street, Jahad Daneshgahi street., alley 4,	
		City	Qom	
Purpose	Treatment	Province	Ghoum	
		Postal code	3711675549	
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.	Approval date	2020-09-15, 1399/06/25	
		Ethics committee reference number	IR.MUQ.REC.1398.105	
Health conditions studied		<u>1</u>		
Age	From 1 year old	Description of health condition studied		
		Cutaneous leishmaniasis		
Gender	Both	ICD-10 code		
		B55.1		
Phase	3	ICD-10 code description		
		Cutaneous leishmaniasis		
Primary outcomes		<u>1</u>		
Groups that have been masked		Description		
No information		En measuring surface of healed tissue of people with cutaneous leishmaniasis		
Sample size	Target sample size: 476 Actual sample size reached: 476	Timepoint		
		Six weeks after the last treatment in both groups, skin lesions are assessed.		
Randomization (investigator's opinion)		Method of measurement		
Randomized		Calibrated ruler		
Randomization description		Secondary outcomes		
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 drooped and the bloc number will be selected. this procedure continued to completed the allocation and reached to sample size.		<u>1</u>		
Blinding (investigator's opinion)		Description		
Not blinded		Elimination of inflammatory symptoms and tissue hardness and healing of papules and ulcers are considered as complete recovery.		
Blinding description		Timepoint		
Placebo		Six weeks after the last treatment		
Not used		Method of measurement		
Assignment		Calibrated ruler		
Other design features		Intervention groups		
Secondary Ids		<u>1</u>		
empty		Description		
Ethics committees		cryotherapy simultaneously with intralesional injection of Glucantime®		
<u>1</u>		Category		
Ethics committee		Treatment - Drugs		
Name of ethics committee				
Ethics committee of Qom University of medical				

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 Saghaipour

Street address

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

City

Qom

Province

Ghous

Postal code

3711675549

Phone

+98 25 3281 3151

Email

abed.saghafi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Abedin Saghaipour

Street address

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

City

Qom

Province

Ghous

Postal code

3711675549

Phone

+98 25 3281 3151

Email

abed.saghafi@yahoo.com

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 Saghaipour

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Entomology

Street address

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

City

Qom

Province

Ghous

Postal code

3711675549

Phone

+98 25 3281 3151

Email

abed.saghafi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Abedin Saghaipour

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Entomology

Street address

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

City

Ghous

Province

Ghous

Postal code

3711675549

Phone

+98 25 3281 3151

Email

abed.saghafi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Ghoum 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

Street address

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

City

Qom

Province

Ghoum

Postal code

3711675549

Phone

+98 25 3281 3151

Email

abed.saghafi@yahoo.com

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