

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of efficacy of topical niosomal 2 % zinc sulfate plus intralesional glucantime in comparison with cryotherapy PLUS intralesional glucantime in the treatment of acute cutaneous leishmaniasis.

Protocol summary

Study aim

Comparing intra-lesional Glucantime plus Niosomal Zinc Sulfate to intra-lesional Glucantime plus Cryotherapy in acute form of cutaneous leishmaniasis

Design

This is a phase 2-3, Two-arm parallel group randomized trial with blinded outcome assessor

Settings and conduct

This is a randomized control study on 64 patients with cutaneous Leishmaniasis in Afzalipour Hospital, Kerman-Iran. Patients were categorized in two groups A and B whom were treated with weekly intralesional meglumine antimonite plus twice daily niosomal topical zinc sulphate and weekly intralesional glucantime plus every other week cryotherapy respectively. This study is a double-blind based on outcome assessor and analyzer

Participants/Inclusion and exclusion criteria

Inclusion criteria were patients with duration of disease less than 6 months and with washout period of 3 month. Exclusion criteria were pregnancy, lactation, patients younger than 2 years old, those with more than 5 lesions, lesions greater than 5 cm, lesions on the face and joint areas and history of sensitization to zinc sulphate or glucantime.

Intervention groups

Patients in group A were treated with weekly intralesional meglumine antimonite (Glucantime) plus twice daily niosomal topical zinc sulphate. Patients in group B received weekly intralesional glucantime plus cryotherapy

Main outcome variables

Complete cure was based on negative leishmaniasis smear. Treatment response was categorized into 3 groups: complete response (100% clinical improvement with negative smear result), partial response (clinical improvement more than or equal to 60%), no response

(clinical improvement less than 60% or increased lesion size). Side effects were evaluated during treatment visits.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170806035524N4**

Registration date: **2018-05-07, 1397/02/17**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-07, 1397/02/17**

Update count: **0**

Registration date

2018-05-07, 1397/02/17

Registrant information

Name

Hoda Badakhsh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 3322 2250

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of efficacy of topical niosomal 2 % zinc sulfate plus intralesional glucantime in comparison with cryotherapy PLUS intralesional glucantime in the treatment of acute cutaneous leishmaniasis.

Public title
evaluation of topical niosomal zinc sulphate in leishmaniasis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
acute cutaneous leishmaniasis(urban type) duration less than 6 months wash out period of 1 month
Exclusion criteria:
pregnancy nursing age less than 2 years old number of lesions more than 5 sensitization to zinc sulphate or glucantime lesions on face or joint lesions larger than 5 centimeter

Age
From 2 years old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: 64

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
double-blind; Outcome assessor and analyser would be blinded

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Ebne sins Ave.,Tahmasb abad Blvd., KermanTown

City

kerman

Province

Kerman

Postal code

Approval date

2016-08-22, 1395/06/01

Ethics committee reference number

IR.Kmu.AH.REC.1395.6

Health conditions studied

1

Description of health condition studied

Acute cutaneous leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes

1

Description

Reduction in induration of the lesion

Timepoint

at BASE -LINE AND IN 2,4,6,8,10,12 WEEKS and 3 months after end of the treatment

Method of measurement

by measuring induration of the lesions (largest diameter) by transparent paper

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:treatment of cutaneous leishmaniasis with weekly intralesional glucantime plus twice daily niosomal topical zinc sulphate

Category

Treatment - Drugs

2

Description

Control group: treatment of cutaneous leishmaniasis with weekly intralesional glucantime plus every other week

cryotherapy
Category
Treatment - Drugs

Country of origin
Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Afzalipour hospital, Imam high way, Kerman
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Abbas pardakhty
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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

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
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Mahin aflatoonian
Position
Assistant professor of dermatology
Latest degree
Subspecialist
Other areas of specialty/work
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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

analytic data (without personal recognizable data) can
be shared with other researchers.

When the data will become available and for how long

6 months after article publication

To whom data/document is available

accessibility of data can be allowed for academic
research centers

Under which criteria data/document could be used

for more research in treatment of leishmaniasis

From where data/document is obtainable

via email of corresponding author

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

after agreement between authors of the article ,data will
be sent to applier via e-mail

Comments