

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Efficacy of intra-lesional injections of meglumine antimoniate once a week vs. twice a week in the treatment of cutaneous leishmaniasis caused by *L. tropica* in Iran

Protocol summary

Study aim

Efficacy of intra-lesional injections of meglumine antimoniate once a week vs. twice a week in the treatment of cutaneous leishmaniasis caused by *L. tropica*

Design

Patients were randomly allocated to one of two intervention groups. The two intervention groups included intra-lesional injections of meglumine antimoniate (IL-MA) produced by Sanofi-Aventis, France, once a week or twice a week. IL-MA injection is performed using a 30G needle head in each lesion. The dose of the injection MA is between 0.2 and 1.5 ml per lesion depending on the size of the lesion. This treatment will continue for a maximum of 12 weeks or until the lesion heals before the end of the study (12 weeks).

Settings and conduct

Mashhad is an endemic area for ACL. The city is home to more than 3 million people. Millions of pilgrims from all over the world visit the city every year. The city of Bam in Kerman province is also endemic for ACL.

Participants/Inclusion and exclusion criteria

Patients with clinically suspected CL lesion(s) were screened. Parasitological proven (smear and/or culture) CL patients caused by *L. tropica* were recruited into the study if they met other eligibility criteria. Inclusion criteria: age between 8-70 years, willingness to participate in the trial, and sign in informed consent. Exclusion Criteria: Patients with lesions over 6 months, more than 4 lesions, size of lesions more than 3 cm, lesions on the face or near the vital organ, pregnant patients, patients with a history of systemic treatment and those with acute or chronic

Intervention groups

once a week or twice a week intra-lesional injection of meglumine antimoniate

Main outcome variables

complete cure defined as complete re-epithelialization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20081130001475N13**

Registration date: **2019-12-30, 1398/10/09**

Registration timing: **retrospective**

Last update: **2019-12-30, 1398/10/09**

Update count: **0**

Registration date

2019-12-30, 1398/10/09

Registrant information

Name

Ali Khamesipour

Name of organization / entity

Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 0657

Email address

khamesipour@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-10-07, 1396/07/15

Actual recruitment end date

2018-03-16, 1396/12/25

Trial completion date

2018-03-16, 1396/12/25

Scientific title

Efficacy of intra-lesional injections of meglumine antimoniate once a week vs. twice a week in the treatment of cutaneous leishmaniasis caused by *L. tropica* in Iran

Public title

Randomized trial of local injections for cutaneous leishmaniasis caused by *L. tropica*

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

80-70 year old patients with clinically suspected CL lesion(s) with Parasitological proven (smear and/or culture) CL patients caused by *L. tropica* were recruited into the study if they met other eligibility criteria. Polymerase chain reaction (PCR) was performed on every sample to assure that the lesion was caused by *L. tropica*. Other inclusion criteria were age 8-70 years, willingness to participate in the trial, and sign an informed consent and an oral assent from the children.

Exclusion criteria:

Patients with lesion(s) duration more than 6 months, more than 4 lesions, ulcer size more than 3 cm, lesions on the face or close to a vital organ, pregnant and nursing patients, those with a history of previous systemic or IL treatment with MA or those with an acute or chronic disease that could affect the course of CL or treatment with IL-MA injections were excluded.

AgeFrom **8 years** old to **70 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **180**Actual sample size reached: **180****Randomization (investigator's opinion)**

Randomized

Randomization description

Random sequence was generated using version 16 of SPSS (SPSS Inc. Chicago, IL, USA) software. To conceal the random sequence from the recruiter, sequentially-numbered opaque sealed envelope (SNOSE) was used.

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**

کمیته اخلاق دانشگاه، مرکز آموزش و پژوهش بیمارهای پوست و جذام، دانشگاه علوم پزشکی تهران

Street address

415 Taleghani Avenue

City

Tehran

Province

Tehran

Postal code

1416613675

Approval date

2013-06-23, 1392/04/02

Ethics committee reference number

J/423/2252

Health conditions studied**1****Description of health condition studied**

Leishmania

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

Primary outcomes**1****Description**

primary outcome of the study was complete cure defined as complete re-epithelialization of the lesion with no induration

Timepoint

Before the intervention and every week

Method of measurement

Measurement of the lesion

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Once injection per week

Category

Treatment - Drugs

2

Description

Intervention group: Twice a week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad Health Network

Full name of responsible person

Mohammad Ghoorchi

Street address

Vakilabad Ave

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9919191778

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+98 51 3809 1000

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2

Recruitment center

Name of recruitment center

Bam Health Network

Full name of responsible person

Mohammad Reza Aflatoonian

Street address

SARDARAN Square - Shahid Rajaei Blvd

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mraflatoonian@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

MOHAMMAD ALI SAHRAIAN

Street address

Tehran University of Medical Sciences: No. 226, Qods St., Keshavarz Blvd., Tehran, Iran

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1417653761

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ali Khamesipour

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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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

Lesion measurement and drug side effects

When the data will become available and for how long

Since 1398

To whom data/document is available

Researcher

Under which criteria data/document could be used

Researcher

From where data/document is obtainable

Ali Khamesipour

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

Visit the center and provide reasons for their use

Comments