Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 trail, 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 cutaneousleishmaniasis 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. Polymers 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.
Age
From **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 generatedusing 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 بیماریهای 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
City
Mashhad
Province
Razavi Khorasan
Postal code
9919191778
Phone
+98 51 3809 1000
Fax
Email
GhoorchiMH1@mums.ac.ir

2

Recruitment center
Name of recruitment center
Bam Health Network
Full name of responsible person
Mohammad Reza Aflatoonian
Street address
SARDARAN Square - Shahid Rajaee Blvd
City
BAM
Province
Kerman
Postal code
6715847141
Phone
+98 83 3835 8258
Email
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
City
Tehran
Province
Tehran
Postal code
1417653761
Phone
+98 21 8163 3685
Email
vcr@tums.ac.ir
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
Street address
The Center for Research and Training in Skin Diseases and Leprosy, No. 415, Naderi St., Taleghani Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 2221
Email
ali.khamesipour@gmail.com

Person responsible for scientific 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

Street address
The Center for Research and Training in Skin Diseases and Leprosy, No. 415, Naderi St., Taleghani Ave., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1416613675

Phone
+98 21 8897 2221

Email
ali.khamesipour@gmail.com

Person responsible for updating data

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

Street address
The Center for Research and Training in Skin Diseases and Leprosy, No. 415, Naderi St., Taleghani Ave., Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1416613675

Phone
+98 21 8897 2221

Email
ali.khamesipour@gmail.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
Lesion measurement and drug side effects

When the data will become available and for how long
Since 1398

To whom data/document is available
Reseacher

Under which criteria data/document could be used
Reseacher

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