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: age between 8-70 years, willingness to participate in the trial, and sign in informed consent

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
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. 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 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

Secondary Ids
empty

Ethics committees
1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه، مرکز آموزش و پژوهش بیماری‌های پوست و جدید، 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
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
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
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**Full name of responsible person**
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**Other areas of specialty/work**
Immunology

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**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**
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**Email**
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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**
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**