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
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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. 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

Primary outcomes

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

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
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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
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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
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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