Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessment of the efficacy of the combination of a silver-containing dressing with intralesional meglumine antimoniate injections in comparison with a combination of an inert dressing and intralesional meglumine antimoniate injections and intralesional meglumine antimoniate injections alone in the treatment of cutaneous leishmaniasis due to Leishmania major: A randomized assessor-blind controlled clinical trial

Protocol summary

Summary

Aim:This study is designed to assess of the efficacies of combinations of intralesional injections of meglumine antimoniate (MA) and a silver dressing, intralesional MA and an inert dressing in comparison with the intralesional injections of MA in the treatment of CL due to L. major Study design: Randomized, assessor-blind controlled clinical trial. Duration and Place: 12 months-Kashan Sample size: 120 patients (40 patients in each group) (210 lesions: 70 lesions in each group) Interventions: Group 1: combination of a silver-containing dressing (to be changed every other day) and weekly intralesional meglumine antimoniate injections for 6 weeks; Group 2:combination of an inert dressing (to be changed every other day)and weekly intralesional meglumine antimoniate injections for 6 weeks; Group 3- weekly intralesional meglumine antimoniate injections alone for 6 weeks. Inclusion and exclusioin criteria:Inclusion criteria: a) Parasitollogically proven cases of cutaneous leishmaniasis b) Otherwise healthy c)Age: 12-60 years d) willing to participate in the study. Exclusion criteria: a) Pregnant or lactating women b) Duration of lesions more than 3 months c) Number of lesions more than 5 d) Ulcer size greater than 5 cm in the largest diameter e) History of full course of standard treatment (antimonials) f) Indication for administration of systemic treatment with meglumine antimoniate g) Presence of secondary bacterial infection of the lesion according to clinical appearance of the lesion. Primary outcome: Complete healing of the lesions 6 weeks after the initiation of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138707201166N2**
Registration date: **2008-10-21, 1387/07/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2008-10-21, 1387/07/30

Registrant information

Name

Alireza Khatami

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

akhatami@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2008-09-09, 1387/06/19

Expected recruitment end date
2009-09-09, 1388/06/18
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessment of the efficacy of the combination of a silver-containing dressing with intralesional meglumine antimoniate injections in comparison with a combination of an inert dressing and intralesional meglumine antimoniate injections and intralesional meglumine antimoniate injections alone in the treatment of cutaneous leishmaniasis due to Leishmania major: A randomized assessor-blind controlled clinical trial

Public title
Assessment of the efficacy of dressings in the treatment of cutaneous leishmaniasis due to Leishmania major: A randomized, single-blind controlled clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: a) Parasitollogically proven cases of cutaneous leishmaniasis based on positive smear and/or culture b) Otherwise healthy subjects on the basis of medical history c)Age: 12-60 years d) willing to participate in the study and sign the informed consent (by the patient or his/her/partner/guardian) in case of younger than 18 years Exclusion criteria: a) Pregnant or lactating women b) Duration of lesions more than 3 months c) Number of lesions more than 5 d) Ulcer size greater than 5 cm in the largest diameter e) History of full course of standard treatment (antimonials) f) History of allergy to meglumine antimoniate or silver g) Serious systemic illnesses as judged by the physician h) Participation in any drug trial in the last 60 days i) Indication for administration of systemic treatment with meglumine antimoniate j) Presence of secondary bacterial infection of the lesion according to clinical appearance of the lesion
Age
From **12 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **210**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

1

Registry name
Cochrane Skin Group
Secondary trial Id
CSG Trial No. 51
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of the Center for Research and Training in Skin Diseases and Leprosy, Tehran Unive
Street address
No. 79, Taleqani Avnue
City
Tehran
Postal code
12675-14166
Approval date
2007-11-30, 1386/09/09
Ethics committee reference number
1625/423/چ

Health conditions studied

1

Description of health condition studied
Cutaneous leishmaniasis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Complete healing
Timepoint
at 6 weeks after initiation of the intrvention(s)
Method of measurement
Lesions' assessment of healing by measuring the size of induration and ulcer

Secondary outcomes

1

Description
Complete healing

Timepoint
at 6 months after initiation of the intervention(s)
Method of measurement
Lesions' assessment of healing by measuring the size of induration and ulcer

2

Description
Adverse Effects
Timepoint
Recorded at each follow-up visit
Method of measurement
Taking medical history and performing physical examination

Intervention groups

1

Description
Group 1-Weekly intralesional injection of meglumine antimoniate (Glucantime, Rhodia Laboratories, rhone Polenc, France) up to six consecutive weeks or complete healing of the lesion Group/2-Weekly intralesional injection of meglumine antimoniate (Glucantime, Rhodia Laboratories, Rhone Polenc, France) up to six consecutive weeks or complete healing of the lesion plus every other day application of an inert dressing (Atrauman, Hartmann CMC Consumer Medical Care GmbH, Heidenheim, Germany) on each lesion for six consecutive weeks or complete healing/Group 3-Weekly intralesional injection of meglumine antimoniate up to six consecutive weeks or complete healing of the lesion plus every other day application of a silver containing (Atrauman Ag, Hartmann CMC Consumer Medical Care GmbH, Germany, Heidenheim, Germany) dressing on each lesion for six consecutive weeks or complete healing
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Golabchi Clinic
Full name of responsible person
Alireza Firooz, MD
Street address
Imam Khomeini Street
City
Kashan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Alireza Firooz, MD
Street address
Center for Research and Training in Skin Diseases and Leprosy, No.79, Taleqani Avenue
City
Tehran
Grant name
Grant code / Reference number
Project number: 87/01/03/6766-Contract number 132/344
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences
Full name of responsible person
Alireza Firooz, MD
Position
Associate Professor of Dermatology
Other areas of specialty/work
Street address
No 79, Taleqani Avenue
City
Tehran
Postal code
14166-13675
Phone
+98 21 8897 8190
Fax
+98 21 8896 3804
Email
firozali@sina.tums.ac.ir
Web page address
-

Person responsible for scientific inquiries

Contact
Name of organization / entity
Center for Resarch and training in Skin Diseases and Leprosy, Tehran University of Medical Sciences

Full name of responsible person
Alireza Firooz, MD
Position
Associate Professor of Dermatology
Other areas of specialty/work
Street address
No 79, Taleqani Avenue
City
Tehran
Postal code
14166-13675
Phone
+98 21 8897 8190
Fax
+98 21 8896 3804
Email
firozali@sina.tums.ac.ir
Web page address
-

Person responsible for updating data

Contact
Name of organization / entity
Center for Research and Training in Skin Diseases and Leprosy, Tehran University of Medical Sciences
Full name of responsible person
Alireza Firooz, MD
Position
Associate Professor of Dermatology
Other areas of specialty/work
Street address
No 79, Taleqani Avenue
City
Tehran
Postal code
14166-13675
Phone
+98 21 8897 8190
Fax
+98 21 8896 3804
Email
firozali@sina.tums.ac.ir
Web page address
-

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty