

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Randomized, double blind, phase 3 clinical trial of efficacy and safety of radio wave-induced heat therapy plus topical liposomal Amphotericin B in comparison with heat therapy plus placebo for the treatment of zoonotic cutaneous leishmaniasis caused by Leishmania major

Protocol summary

Summary

1) Objectives -To evaluate the efficacy and safety of heat therapy plus topical nano-liposomal form of Amphotericin B compared with heat therapy plus placebo for the treatment of zoonotic cutaneous leishmaniasis (ZCL) caused by Leishmania major. -To evaluate the efficacy and safety of heat therapy for the treatment of zoonotic cutaneous leishmaniasis (ZCL) caused by Leishmania major (2)Design A randomized double blind comparative, efficacy and safety study. (3)setting and conduct Male and female volunteers aged 12-60 years, with ZCL caused by Leishmania major from an endemic area of ZCL in Iran will be recruited. ZCL diagnosis will be based on parasitologically proven cases of cutaneous leishmaniasis (CL) and the species will be confirmed by PCR. (4)Participants including major eligibility criteria Inclusion:Males & females 12-60 years of age. Parasitological proven CL caused by L. major (identification is done by using PCR). Exclusion:Pregnant or lactating women, Concurrent or chronic illness based on previous history, Duration of lesion more than 3 months, Number of lesions more than 5,Ulcer size greater than 3 cm in their largest diameter. (5)Intervention A)Heat therapy machine using current field radio frequency generator (ThermoMed™ 1.8TM, 140 Thermosurgery Technologies Inc., Phoenix, USA) already was donated by WHO to PI for another study. B)Topical nano-liposomal Amphotericin B 0.4% (SinaAmpholeish): (6)Outcomes Primary outcome:Complete cure, defined as complete reepithelization of the lesion and loss of induration. Secondary outcome:Partial cure, More than 50% reduction in size or induration compared tBatch baseline.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510031475N8**

Registration date: **2017-06-11, 1396/03/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-11, 1396/03/21

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

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

Expected recruitment start date

2016-12-15, 1395/09/25

Expected recruitment end date

2017-12-15, 1396/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized, double blind, phase 3 clinical trial of efficacy and safety of radio wave-induced heat therapy plus topical liposomal Amphotericin B in comparison with heat therapy plus placebo for the treatment of zoonotic cutaneous leishmaniasis caused by Leishmania major

Public title

Efficacy of heat therapy plus topical liposomal Amphotericin B for the treatment of cutaneous leishmaniasis caused by Leishmania major

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Males & females 12-60 years of age;Parasitologically proven CL caused by L. major (identification is done by using PCR); Otherwise healthy subjects on the basis of medical history; physical examination and results of blood test if requested by the physician; Ability to understand the principles of the trial and Signing an informed consent voluntarily and knowingly. Exclusion Criteria: Pregnant or lactating women; Concurrent or chronic illness based on previous history;Duration of lesion more than 3 months;Number of lesions more than 5;Ulcer size greater than 3 cm in their largest diameter; History of full course of standard treatment (antimonials); Involvement in any other drug or vaccine trial during the study period.

Age

From **12 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Cohort Study

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences Ethical Committee

Street address

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Isfahan, Iran.Khoram St,Jomhuri Sq,Postal Code:81876-98191.Isfahan,Iran.

City

Isfahan

Postal code

81876-98191

Approval date

2016-11-09, 1395/08/19

Ethics committee reference number

495057

2**Ethics committee****Name of ethics committee**

Shiraz University of Medical Sciences, Ethic committee office

Street address

Shiraz University of Medical Sciences

City

Shiraz

Postal code**Approval date**

2016-12-18, 1395/09/28

Ethics committee reference number

IR.SUMS.REC.1395.157

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

Cutaneous Leishmaniasis

ICD-10 code

B55.1

ICD-10 code description

Cutaneous leishmaniasis

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

Reepithelization of the lesions/Complete cure

Timepoint

Monthly

Method of measurement

Lesion measurement/Digital photos

Secondary outcomes

1

Description

Partial cure : Decrease size of the lesions

Timepoint

Monthly

Method of measurement

Lesion measurement /Digital photos

Intervention groups

1

Description

Heat therapy

Category

Treatment - Devices

2

Description

Topical nano-liposomal Amphotericin B 0.4% (SinaAmpholeish) twice a day for 28 days

Category

Treatment - Drugs

3

Description

Placebo Gel without liposomes or Amphotericin B

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences,

Full name of responsible person

Dr. Fatemeh Sokhanvari

Street address

City

Isfahan

2

Recruitment center

Name of recruitment center

Parasitology department, Medical School, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Hatam

Street address

Parasitology department, Medical School, Shiraz University of Medical Sciences, Zand St, Shiraz, Iran.

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development (NIMAD)

Full name of responsible person

Dr. Ghaffari

Street address

No.21, Besat St., Fatemi Av., Tehran, Iran.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

National Institute for Medical Research Development (NIMAD)

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

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

Full name of responsible person

Prof. Ali Khamesipour

Street address

No. 415, Taleghani St., Tehran Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Proportion provided by this source

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

3

Sponsor

Name of organization / entity

Skin Diseases and Leishmaniasis Research Center (SDLRC), Isfahan University of Medical Sciences

Full name of responsible person

Dr.Fatemeh Sokhanvari MD

Street address

Khoram St., Jomhouri Sq., Isfahan, Iran.

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Skin Diseases and Leishmaniasis Research Center (SDLRC), Isfahan University of Medical Sciences

Proportion provided by this source**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

4

Sponsor

Name of organization / entity

Exir Nano Sina CO.

Full name of responsible person

Dr. MahmoudReza Jafaari

Street address

Unit 7, No.94, FathiShaghaghi St, Jahanmehr St, Gomnam Ave, Fatemi Sq.,

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Exir Nano Sina CO.

Proportion provided by this source**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

1.Skin Disease and Leishmaniasis Research Center, Isfahan University of Medical Sciences 2 Parasito

Full name of responsible person

1.Dr.Fatemeh Sokhanvari MD 2.Dr. Gholamreza Hatam

Position

Doctor

Other areas of specialty/work**Street address**

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City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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

Full name of responsible person

Prof. Ali Khamesipour

Position

Prof./PhD

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Person responsible for updating data

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Name of organization / entity

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

Full name of responsible person

Prof. Ali Khamesipour

Position

Prof

Other areas of specialty/work**Street address**

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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