

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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**

1.Isfahan University of Medical Sciences, Khoram St, Jomhouri Sq, Isfahan, Iran. 2.Parasitology department, Medical School, Shiraz University of Medical Sciences, Zand St, Shiraz, Iran.

**City**

1.Isfahan 2.Shiraz

**Postal code****Phone**

1.00983133373736 2.00989173117983

**Fax****Email**

1.dr\_f\_sokhanvari@yahoo.com

2.hatamghr@sums.ac.ir.

**Web page address**

## 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

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

No.415 Taleghani St, Tehran, Iran.

**City**

Tehran

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+98 21 8897 0658

**Fax****Email**

ali.khamesipour@gmail.com

**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 Science

**Full name of responsible person**

Prof. Ali Khamesipour

**Position**

Prof

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

No. 415, Taleghani St., Tehran, Iran.

**City**

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**Fax**

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**Email**

khamesipour\_ali@yahoo.com

**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*