

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 2026

**Evaluations of phase II double blind randomized controlled clinical trial, single dose of the gentamicin-attenuated line of Leishmania major H-line vaccine against cutaneous leishmaniasis in comparison with phosphate buffer saline control group in Sabzevar and Sarakhs located in Razavi Khorasan Province in east of Iran**

### Protocol summary

#### Summary

A live attenuated line of Leishmania major (L. major H-line) has been established by culturing promastigotes in vitro under gentamicin pressure. Aim: This study was designed to investigate the safety and protection of the attenuated line of Leishmania major vaccine. A randomised, double-blind, controlled trial with 2-year follow-up after the administration a single dose of vaccine. The present study was carried out in some endemic areas of cities of Sabzevar and Sarakhs, located Razavi Khorasan Province in east of Iran, which have a population of about 230 000 and 35 000 respectively. A total of 1790 healthy males and females aged: 3-75 years old volunteers were received the attenuated line vaccine or placebo. Interventions: All volunteers or child's parents were understood and the consent form willingly to participate in the study were signed by volunteers or child's parents (under 18 year). Sequentially numbered identical-looking vials of vaccine or PBS were produced. A random list of codes for vials were prepared. Volunteers were inoculated intradermally 0.1 mL of the attenuated of L. major or PBS (0.1 ml) in the deltoid area of their right hands. The codes were kept sealed until the end of the 2-year follow-up..Inclusion and exclusion criteria: Inclusion criteria: Otherwise healthy, exclusion criteria: History of leishmaniasis or any scar resembling cutaneous leishmaniasis. Primary outcome: Immunity to cutaneous leishmaniasis. During the follow-up period 24 month, suspected cutaneous lesions lasting for more than 4 weeks have been examined by routine laboratory methods.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2015101924604N1**

Registration date: **2017-04-20, 1396/01/31**

Registration timing: **na**

Last update:

Update count: **0**

#### Registration date

2017-04-20, 1396/01/31

#### Registrant information

##### Name

Hamid Daneshvar

##### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3222 3016

##### Email address

hamid.daneshvar@glasgow.ac.uk

#### Recruitment status

**Not enough for processing**

#### Funding source

Kerman University of Medical Sciences

#### Expected recruitment start date

2015-11-20, 1394/08/29

#### Expected recruitment end date

2007-11-20, 1386/08/29

#### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluations of phase II double blind randomized controlled clinical trial, single dose of the gentamicin-attenuated line of Leishmania major H-line vaccine against cutaneous leishmaniasis in comparison with phosphate buffer saline control group in Sabzevar and Sarakhs located in Razavi Khorasan Province in east of Iran

**Public title**

Evaluation of phase II randomised vaccine trial of single dose of the gentamicin-attenuated line of Leishmania major H-line against cutaneous leishmaniasis in Sabzevar and Sarakhs in east of Iran

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion and exclusion criteria: Inclusion criteria: Otherwise healthy; age: 3-75 years; sign the consent form willingly to participate in this study. Exclusion criteria: History of leishmaniasis or any scar resembling cutaneous leishmaniasis; pregnant; acute or chronic disease; history of allergic; history of vaccination in the previous month; immune deficiency or immune suppression therapy.

**Age**From **3 years** old to **75 years** old**Gender**

Both

**Phase**

2

**Groups that have been masked***No information***Sample size**Target sample size: **1790****Randomization (investigator's opinion)**

Randomized

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

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

**Ethics committees**1**Ethics committee**

Name of ethics committee

Kerman University of Medical Sceinces

**Street address**

Kerman University of Medical Sceinces

**City**

Kerman

**Postal code****Approval date**

2015-11-23, 1394/09/02

**Ethics committee reference number**

IR.KMU.REC.1394.244

**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**

Immunity to cutaneous lesions

**Timepoint**

After vaccination

**Method of measurement**

Observation, taking sample and examination by routine methods with direct smear r

**Secondary outcomes**1**Description**

redness and induration at the site of injection,

**Timepoint**

after vaccination

**Method of measurement**

Measuring the size of induration by ruller,

**Intervention groups**1**Description**

Sequentially numbered identical-looking vials of suspension of promastigotes or PBS were produced. A random list of codes for vials were prepared. Volunteers were inoculated intradermally promastigotes (0.1 ml) in the deltoid area of their right hands.

**Category**

Placebo

2**Description**

Sequentially numbered identical-looking vials of vaccine or phosphate buffer saline (PBS) were produced. A random list of codes for vials were prepared. Volunteers were inoculated intradermally PBS (0.1 ml) in the deltoid area of their right hands.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kerman University of Medical Sciences

##### Full name of responsible person

Dr Hamid Daneshvar

##### Street address

Medical faculty Kerman University of Medical Sciences

##### City

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Dr Pardakhti

##### Street address

Kerman University of Medical Sciences

##### City

Kerman

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kerman 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

Kerman University of Medical Sciences

##### Full name of responsible person

Hamid Daneshvar

##### Position

Immunoparasitology/ PI

##### Other areas of specialty/work

##### Street address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kerman University of Kerman University

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## Person responsible for updating data

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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*