

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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Name of organization / entity

Kerman University of Medical Sciences

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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

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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**

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Full name of responsible person

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Position

Immunoparasitology/ PI

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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