Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Phase I, open clinical vaccine trial study, single dose to evaluate the safety, immunogenicity and efficacy of the gentamicin-attenuated line of Leishmania major H-line against Leishmania major wild-type in volunteers in Kerman

Protocol summary

Study aim
Determination of safety, immunogenicity and protective potency of attenuated Leishmania major H-line vaccine in volunteers

Design
The study was designed as Phase 1, open-label, placebo-controlled clinical trial initially on 27 healthy adult volunteers.

Settings and conduct
Clinical trial conducted in a non-endemic area of Kerman, Iran. A total 27 healthy adult volunteers were enrolled. The ethical principles set forth in the Declaration of Helsinki. Ethical approval was obtained from the Kerman University of Medical Sciences Ethical Committee in 2016 (Ethical code: IR.KMU. REC.1394-106). Written or oral Informed Consent Form (ICF) was obtained from all participants prior to enrollment. A negative LST was performed prior to vaccination. Subjects were screened for health status on medical history, vital signs, medical history, and laboratory examination results (including kidney, liver functions, diabetes and HIV). 0.1 ml vaccine at concentration of 30 × 106 cell/ml in PBS into their right deltoid area. A control injection of PBS was administered (i.d.) into deltoid area of their left arms. After 6 months, 25 subjects were challenged with L. major wild type (6 × 106 cell/ml) into the right forearm of each subject.

Participants/Inclusion and exclusion criteria
Inclusion criteria Healthy; age: 18-60 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.

Intervention groups
For evaluation protection of vaccine, Volunteers were vaccinated with the attenuated live Leishmania major vaccine

Main outcome variables
Determination safety and Immunogenicity of the attenuated Leishmania major

General information

Reason for update

Acronym
GALM

IRCT registration information
IRCT registration number: **IRCT20151019024604N4**
Registration date: **2026-02-03, 1404/11/14**
Registration timing: **retrospective**

Last update: **2026-02-03, 1404/11/14**
Update count: **0**

Registration date
2026-02-03, 1404/11/14

Registrant information

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Name of organization / entity
Kerman University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2015-06-09, 1394/03/19
Expected recruitment end date
2017-06-10, 1396/03/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Phase I, open clinical vaccine trial study, single dose to evaluate the safety, immunogenicity and efficacy of the gentamicin-attenuated line of Leishmania major H-line against Leishmania major wild-type in volunteers in Kerman

Public title
Safety, immunogenicity, and efficacy of a gentamicin-attenuated Leishmania major vaccine in an open-label clinical vaccine trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Healthy male and female Age 18-60 years old Sign the consent form willingly to participate in this study
Exclusion criteria:
History or clinical signs (scars) of cutaneous leishmaniasis (CL) Pregnancy Acute or chronic disease history of allergic History of vaccination in the previous month Immune deficiency or immune suppression therapy
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **27**
More than 1 sample in each individual
Number of samples in each individual: **27**
27 volunteers
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
No

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Kerman University of Medical Sciences and Health Services
Street address
Jahad Blvd. Ebn Sina Avenue
City
Kerman
Province
Kerman
Postal code
7616913555
Approval date
2015-05-27, 1394/03/06
Ethics committee reference number
IR.KMU. REC.1394.106

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
Evaluation safety of vaccine
Timepoint
Usually after intervention for 2 years
Method of measurement
Measuring any adverse events such as redness, induration and lesion. Measuring hematological and biochemical parameters for evaluation liver and kidney functions.

Secondary outcomes

1

Description
The attenuated line of L. major vaccine activated cellular immunity which induced 92% protective efficacy against clinical infection
Timepoint
Usually reached 4 weeks after immunization
Method of measurement
Immunological assessments: Measuring anti-Leishmania

IgG prior and post vaccination, Leishmanin Skin Test, gene expression cytokine (IL-12, IFN-γ) and toll like receptor (TLR2,4,9).Leishmanization (challenge with wild type Leishmania major), for investigation the ability of vaccine to protection, and measuring size of lesion, if developed.

Intervention groups

1

Description

The intervention group: Promastigotes of the attenuated line of Leishmania major were grown in RPMI-1640 medium (Sigma-Aldrich) supplemented with 10% FBS (Labtech International). Cells were harvested, washed with Phosphate-Buffered Saline (PBS), and re-suspended to 20 million cell/ml in PBS containing 7.5% glycerol and glycose. The suspension was dispersed in 1 ml volume aliquots, which cryopreserved using controlled slow-freezing protocol and maintained in liquid nitrogen until the time of use. For inoculation, vials were rapidly thawed and used for intradermal (i.d.) injection. The subjects received a single intradermal injection of 0.1 ml suspensions of cells at concentration of 30 million cell/ml in PBS into their right deltoid area.

Category

Prevention

2

Description

Control group: The subjects received intradermal injection of 0.1 ml sterile phosphate-buffered saline (PBS) into their left deltoid area of their left arms.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kerman Medical University
Full name of responsible person
Hamid Daneshvar
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Dr Hamid Sharifi
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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
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hamid Daneshvar
Position
Associate professor
Latest degree
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Other areas of specialty/work
Immunology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Following details are available: Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report

When the data will become available and for how long

Data are ready after submission paper

To whom data/document is available

This available for people working in academic institutions

Under which criteria data/document could be used

After publishing data

From where data/document is obtainable

After submission in Journal

What processes are involved for a request to access data/document

All details of study will be published.

Comments

The Phase 1 clinical trial is being registered retrospectively to meet journal publication requirements and to ensure complete public documentation of all phases of the vaccine’s clinical development. Although the Phase 1 study was conducted earlier, the subsequent Phase 2 and Phase 3 clinical trials for this vaccine were prospectively registered, completed, and finalized approximately two years ago. Registering the Phase 1 trial at this time ensures transparency and consistency across all trial phases and aligns with WHO and ICMJE recommendations for trial registration