

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Effectiveness of wet-cupping in treatment of BALB/c-mice infected by Leishmania major. Pilot Randomized Clinical Trial

Protocol summary

Summary

Cutaneous leishmaniasis (CL) caused by Leishmania major is common in Middle East countries. Most therapies are limited and there is no effective vaccine for leishmaniasis. It has been reported that wet-cupping (a Complimentary and Alternative Medicine technique) has been effective in treatment of drug resistant CL. This study aim is to determine the efficacy of wet-cupping in treatment of L. major infected BALB/C mice. We have designed a randomized clinical trial with 6 mice in each experimental and control group. This study will perform at medical laboratory in Kermanshah University of Medical Science. 12 male BALB/c mice, aged 8-10 weeks, will be used (six mice for each experimental and control group). Each mouse will be infected with L. major on left hind footpad. Mice in intervention group will undergo wet-cupping once a week, up to 6 weeks. Footpad thickness index will be measured for continues 7 weeks in both groups. Moreover, spleen and lymph node cell culture will be done at week 9 after inoculation. Levels of IFN- γ and IL-4 will be measured as the markers of TH1 and TH2, respectively.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201306021310N9**
Registration date: **2013-06-03, 1392/03/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-06-03, 1392/03/13

Registrant information

Name

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Name of organization / entity

Kermanshah University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Science

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of wet-cupping in treatment of BALB/c-mice infected by Leishmania major. Pilot Randomized Clinical Trial

Public title

Effectiveness of wet-cupping on cutaneous leishmaniasis

Purpose

Treatment

Inclusion/Exclusion criteria

male BALB/c mice, aged 8-10 weeks

Age

From **8 years** old to **10 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 12

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blv

City

Kermanshah

Postal code**Approval date**

2012-12-21, 1391/10/01

Ethics committee reference number

911045

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**

Footpad thickness index

Timepoint

Weekly for continues 7 weeks

Method of measurement

Vernier caliper

2**Description**

Spleen and lymph node cell culture

Timepoint

Week 9

Method of measurement

Spleen and lymph node cell culture

3**Description**Levels of IFN- γ and IL-4**Timepoint**

Week 9

Method of measurementIFN- γ and IL-4 levels in supernatant**Secondary outcomes**

empty

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

Wet-cupping

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**Medical laboratory in Kermanshah University of
Medical Science**Full name of responsible person****Street address****City**

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Nourizad

Street address

Kermanshah University of Medical Sciences

City

Kermanshah

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

Yes

Title of funding source
Kermanshah 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

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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