Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

A comparison between therapeutic efficacy of wet-cupping vs. conventional treatment in patients with chronic non-specific low back pain.

Protocol summary

Summary

Aim: A comparison between therapeutic efficacy of wet-cupping vs. conventional treatment in patients with chronic non-specific low back pain. Design: A controlled, single center, randomized clinical trial. Studied population: Patients between 16-65 years of age with chronic nonspecific low back pain persisting for at least 4 weeks. Sample size: 150 cases. Intervention: -In intervention group: The treatment itself will be performed by a physician using standard techniques in medical centers. Wet-cupping will be applied in 2 stages: between the two scapulas in the first day and in the sacrum area in 2 weeks; Each wet-cupping treatment procedure will last about 20 min and will be conducted in five steps. -In control group: control group will receive the standard conventional treatment for low back pain. This treatment includes: (1) encouragement for early return to usual activities, excluding heavy manual labor, (2) activity alteration to minimize symptoms, (3) medical therapy: e.g., acetaminophen or NSAIDs, (4) short duration muscular relaxants, (5) bed rest not more than 2 days. Outcomes: Primary outcome includes Disability and quality of life index using ODI (Oswestry disability index), and secondary outcome will be the Pain intensity using VAS (Visual analogue scale).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302167274N7**
Registration date: **2013-02-18, 1391/11/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-18, 1391/11/30

Registrant information

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Mohsen Mardani Kivi
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Guilan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Science

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2013-03-05, 1391/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison between therapeutic efficacy of wet-cupping vs. conventional treatment in patients with chronic non-specific low back pain.

Public title

Chronic non-specific low back Pain: comparing the efficacy of wet-cupping and conventional treatment.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 16-65 years; Low back pain persisting for 4 weeks or more. Exclusion criteria: possible spinal pathology (e.g., carcinoma); severe or progressive motor weakness or central disc prolapse in the last 3 years; bleeding disorders (coagulopathies such as hemophilia) and history of treatment with wet-cupping in the last 6 months; radicular or referral back pain with probable discopathy disorders; VAS score lower than 4; and localized tenderness on the spinal process.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Guilan University of Medical Sciences

Street address

Vice chancellor for research, Guilan University of Medical Sciences, Namjou avenue

City

Rasht

Postal code

Approval date

2012-10-23, 1391/08/02

Ethics committee reference number

1910231215

Health conditions studied

1

Description of health condition studied

Low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain, Loin pain, Low back strain

Primary outcomes

1

Description

Disability index

Timepoint

Baseline assessment, post treatment and final follow-up visit.

Method of measurement

Oswestry Disability Index

Secondary outcomes

1

Description

Pain intensity

Timepoint

Baseline assessment, post treatment and final follow-up visit.

Method of measurement

Visual analogue scale

Intervention groups

1

Description

In intervention group: The treatment itself will be performed by a physician using standard techniques in a medical center. Wet-cupping will be applied in 2 stages: between the two scapulas in the first day and in the sacrum area in 2 weeks; each wet-cupping treatment procedure will last about 20 min and will be conducted in five steps.

Category

Treatment - Devices

2

Description

In control group: control group will receive the standard conventional treatment for low back pain. This treatment includes: (1) encouragement for early return to usual activities, excluding heavy manual labor, (2) activity alteration to minimize symptoms, (3) medical therapy: e.g., acetaminophen, or NSAIDs, (4) short duration muscular relaxants, (5) bed rest not more than 2 days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam-Reza Clinic of Poursina Hospital
Full name of responsible person
Dr Mohsen Mardani Kivi
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Imam-Reza clinic, Poursina hospital, Parastar avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Guilan University of Medical Sciences
Full name of responsible person
Dr. Abdolrasoul Sobhani, Research chancellor of Guilan university of medical science
Street address
Vice chancellor for research, Guilan University of Medical Sciences, Namjou avenue
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Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Guilan 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