

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The effect of Cupping on nonspecific lumbar pain of the elderly referred to the Iranian Medicine Clinic.

#### Protocol summary

##### Study aim

Determining the effect of Cupping on nonspecific lumbar pain of the elderly referred to the Iranian Medicine Clinic of Kerman University of Medical Sciences

##### Design

This clinical trial was designed with 70 patients in two groups of cupping therapy and placebo by a simple random method for 10 days, into every other day in even or odds day to avoid patients of two groups confronting each other. the patients record their probably complications and pain intensity based on vas questionnaire from 0-10 in checklist.

##### Settings and conduct

This study is designed for elderly patients with non-specific low back pain in Kerman traditional Persian medicine clinic.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness and satisfaction of the patient to participate in the study The presence of non-specific musculoskeletal pain in the lower back based on the doctors diagnosis Age>60 years (35) Mild to moderate pain intensity 4-8 on VAS Low back pain>=3 month (8) BMI <35 (34) Exclusion criteria: Back pain caused by trauma inflammatory or malignant disease Presence of coagulopathy disease or anticoagulant agent consumption Existence of radiculopathy symptoms such as radiating pain, paresis, prickling, or tingling of lower limb Serious acute or chronic organic disease such as diabetes, mental disorders Congenital malformation of the spine Treatment with physiotherapy or opiates and other procedures within the last 4 weeks Central Nervous System impairment

##### Intervention groups

This study is an interventional research as a clinical trial. The first group is undergoing cupping therapy and the second group received placebo with slight negative pressure and Double-sided adhesive.

##### Main outcome variables

pain intensity VAS Questionnaire (0-10)

#### General information

##### Reason for update

##### Acronym

CT

##### IRCT registration information

IRCT registration number: **IRCT20200720048152N1**

Registration date: **2023-02-01, 1401/11/12**

Registration timing: **retrospective**

Last update: **2023-02-01, 1401/11/12**

Update count: **0**

##### Registration date

2023-02-01, 1401/11/12

##### Registrant information

##### Name

Zohreh Sarhadinejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 4425 2922

##### Email address

z.sarhadinejad@mubam.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-13, 1401/09/22

##### Expected recruitment end date

2023-01-25, 1401/11/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

The effect of Cupping on nonspecific lumbar pain of the elderly referred to the Iranian Medicine Clinic.

**Public title**

The effect of Cupping on lumbar pain of the elderly

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Willingness and satisfaction of the patient to participate in the study  
The presence of non-specific musculoskeletal pain in the lower back based on the doctors diagnosis  
Age > 60 years (35)  
Mild to moderate pain intensity 4-8 on VAS  
Low back pain >= 3 month (8)  
BMI < 35 (34)

**Exclusion criteria:**

Back pain caused by trauma inflammatory or malignant disease  
Presence of coagulopathy disease or anticoagulant agent consumption  
Existence of radiculopathy symptoms such as radiating pain, paresis, prickling, or tingling of lower limb  
Serious acute or chronic organic disease such as diabetes, mental disorders  
Congenital malformation of the spine  
Treatment with physiotherapy or opiates and other procedures within the last 4 weeks  
Central Nervous System impairment

**Age**

From **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is done in a simple way using a table of random numbers. The collaborator of the Project, who does not intervene in the research process, first prepares pockets according to sample size and numbers them, then based on the table of random numbers, randomly select a number and read the entire column below it vertically. The numbers whose right two digits are between 01 to 70 up to 35 numbers are placed in cupping therapy group and the rest are assigned to the placebo group. The type of treatment is written in each envelope and envelopes are closed and sealed. A four-digit code is written on each envelope. Two digits on the left correspond to the order of patient's entry into the study and completes the informed consent form, are added to the first digits. An envelope is opened and the assigned group and day of visit is specified for that patient.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to blind the study, The collaborator of the project, who was not involved in the treatment process or the data analysis process, puts the patients into two groups by a simple random method and using a sealed envelope. The first group is treated with dried cupping, and the second group is treated with placebo (cupping glasses are placed on the skin with a slight negative pressure and use of glue).

**Placebo**

Used

**Assignment**

Other

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

empty

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

Research Ethics Committees of Kerman University of Medical Sciences

**Street address**

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

**City**

Kerman

**Province**

Kerman

**Postal code**

7616913555

**Approval date**

2022-12-12, 1401/09/21

**Ethics committee reference number**

IR.KMU.REC.1401.389

**Health conditions studied****1****Description of health condition studied**

low back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

کمردرد

**Primary outcomes****1****Description**

low back pain intensity

**Timepoint**

registration of daily pain intensity from day 0-10

**Method of measurement**

Visual Analog Scale questionnaire: VAS (0-10)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After random allocation of patients in to two groups of cupping therapy and placebo, in cupping therapy group, 4-10 acrylic cups with a diameter of 25-50 mm were used, the air inside them was heated by the flame of alcohol cotton and the cups were placed on paravertebral region at a distance between I1 and I5 in parallel, for 7-10 minutes. As the air inside the cup cools down and creates suction, the skin is drawn into the cup due to the created vacuum. In such a way that the skin turns from bright red to dark pink. The duration of treatment is 10 days, into every other day in even or odds day to avoid patients of two groups confronting each other. Generally, each person is subjected to 5 sessions. If analgesics are needed, matching is done in both groups.

#### Category

Treatment - Devices

### 2

#### Description

Control group: In the placebo group, by a manual cupping machine with a single suction and double adhesive support, 4-10 acrylic cups with a diameter of 25-50 mm, are attached only to the suction position on both sides of the vertebral column and in parallel at a distance between I1 and I5 (without changing the color of the skin). The cups are removed after 7-10 minutes. The duration of treatment is 10 days, into every other day in even or odds day to avoid patients of two groups confronting each other. Generally, each person is subjected to 5 sessions. If analgesics are needed, matching is done in both groups.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Traditional Medicine clinic

##### Full name of responsible person

Ali Sarhadinejad

##### Street address

No. 1, Emam Jome Ave, Kerman

##### City

kerman

##### Province

Kerman

##### Postal code

7616913550

##### Phone

+98 913 443 0643

##### Email

zh.sn285@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Research assistant

##### Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

##### City

Kerman

##### Province

Kerman

##### Postal code

7616913555

##### Phone

+98 34 3132 5829

##### Fax

+98 34 3132 5830

##### Email

smnouhi@yahoo.com

#### Grant name

#### Grant code / Reference number

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

No

#### Title of funding source

with out grant

#### Proportion provided by this source

1

#### 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

Ali Sarhadinejad

##### Position

student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery  
**Street address**  
Kerman University of Medical Sciences, Medical  
University Campus, Haft-Bagh Highway, Kerman, Iran  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7616913555  
**Phone**  
+98 34 3132 5219  
**Fax**  
+98 34 3132 5830  
**Email**  
A.sarhadi74@yahoo.com  
**Web page address**  
<http://kmu.ac.ir/fa/snm>

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Esmat Nouhi  
**Position**  
associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Kerman University of Medical Sciences, Medical  
University Campus, Haft-Bagh Highway, Kerman, Iran  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7616913555  
**Phone**  
091319888576  
**Email**  
smnouhi@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Bam University of Medical Sciences  
**Full name of responsible person**  
Zohreh Sarhadinejad  
**Position**  
associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Traditional Medicine  
**Street address**  
Iran - Bam - Shahid Rajaie Blvd. - Bam university Of  
Medical Sciences & Health Services  
**City**  
Bam  
**Province**  
Kerman  
**Postal code**  
7661771967  
**Phone**  
+98 34 4434 1120  
**Fax**  
+98 34 4434 0847  
**Email**  
zh.sn285@gmail.com  
**Web page address**

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available