Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 bellow 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 l1 and l5 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 l1 and l5 (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

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No. 1,Emam Jome Ave, Kerman

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kerman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Research assistant

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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

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Person responsible for scientific inquiries

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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