# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

# The comparison of the effect of intermittent vacuum in combination with conventional physical therapy and conventional physical therapy on pain intensity , knee range of motion and functional disability in patients with knee osteoarthritis

## Protocol summary


**Summary**

Objectives: The aim of this study is to compare the effect of intermittent vacuum in combination with conventional physical therapy and conventional physical therapy on pain intensity, knee range of motion and functional disability in patients with knee osteoarthritis. Design: This study will be done on twenty -six people with knee OA that assign to the study by convenient sampling. Setting and conduct: The patients randomly will be divided to two groups. Intervention: The first group (control) will be received TENS, US and hot packs and the second group (intervention) will be received intermittent vacuum, in addition to the above treatments in 10 sessions. Cups of intermittent vacuum will be placed on both sides of the knee joint line and device will be set in 150 mbar pressure and pulse mode with two-second cycles. Main outcome measures: The pain intensity by VAS scale, disability, according to the WOMAC questionnaire and range of motion using the software image j will be measured before and after treatment. Major Inclusion and Exclusion criteria: Patients aged between 45 to 65 years old with knee osteoarthritis that are diagnosed by physician and knee osteoarthritis grade 1 to3 according to the Kellgren . Lawrence classification, will participate in this study. They have not received any cupping treatment until present .If the patients have the history of fracture or surgery on knee joint; history of systemic inflammatory disease; Low back pain; neuropathy; myopathy ; knee deformity, the usage of anticoagulant drugs; platelet deficiency or history of corticosteroid injection in knee joint during the past 6 months will be excluded from this study.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015072016532N2**
Registration date: **2016-04-21, 1395/02/02**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2016-04-21, 1395/02/02

**Registrant information**


**Name**

Sara Abolahrari Shirazi

**Name of organization / entity**

Shiraz University of Medical Sciences- Rehabilitation Sciences Faculty

**Country**

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**Recruitment status**

**Recruitment complete**


**Funding source**

Vice chancellor for research, Shiraz University of Medical Sciences


**Expected recruitment start date**

2014-08-23, 1393/06/01

**Expected recruitment end date**

2015-01-20, 1393/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
The comparison of the effect of intermittent vacuum in combination with conventional physical therapy and conventional physical therapy on pain intensity , knee range of motion and functional disability in patients with knee osteoarthritis

**Public title**
The effectiveness of intermittent vacuum in knee osteoarthritis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria:patients aged between 45 to 65 years old with knee osteoarthritis that are diagnosed by physician and knee knee osteoarthritis grade 1 to3 according to the Kellgren . Lawrence classification; without any cupping treatment until present; the presence of knee pain more than 3 months. Exclusion criteria:The history of fracture or surgery on knee joint; history of systemic inflammatory disease; Low back pain; neuropathy; myopathy; knee deformity, the usage of anticoagulant drugs; platelet deficiency; history of corticosteroid injection in knee joint during the past 6 months
**Age**
From **45 years** old to **65 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **26**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Randomization based on block randomization method

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Shiraz University of Medical Sciences
**Street address**
Zand Blv.
**City**
Shiraz
**Postal code**
**Approval date**
2014-06-30, 1393/04/09
**Ethics committee reference number**
CT- P- 9365- 6665

## Health conditions studied

### 1

**Description of health condition studied**
knee osteoarthritis
**ICD-10 code**
M17.9
**ICD-10 code description**
Gonarthrosis, unspecified

## Primary outcomes

### 1

**Description**
Pain intensity
**Timepoint**
Before and after intervention
**Method of measurement**
Using visual analog scale

### 2

**Description**
Disability
**Timepoint**
Before and after intervention
**Method of measurement**
Using WOMAC questionnaire

### 3

**Description**
knee range of motion
**Timepoint**
Before and after intervention
**Method of measurement**
Using digital camera, marker and image j software

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
The intervention group will be received conventional physical treatment (including TENS, US, hot pack) and intermittent vacuum for 10 sessions in two weeks. The patients will perform quadriceps setting exercise. Other

knee exercises as an exercise program will be taught to patients in tenth session. For vacuum therapy, the cups of devices will be located on medial and lateral sides of knee joint. The pressure of vacuum is 150 milibar with duty cycle of 2 seconds. The total time of vacuum therapy is 10 minutes. The frequency and duration of TENS are 2 Hz and 200 milliseconds respectively. The intensity of TENS will be set by patient`s tolerance. The total time of treatment by TENS is 20 minutes. The one MHz ultrasound with intensity of 0.8w/cm² will be used by 5 minutes.Hot pack will be used by 20 minutes.

**Category**

Rehabilitation

**2**

**Description**

The control group will be received conventional physical treatment (including TENS, US, hot pack) for 10 sessions in two weeks. The patients will perform quadriceps setting exercise. Other knee exercises as an exercise program will be taught to patients in tenth session. The frequency and duration of TENS are 2 Hz and 200 milliseconds respectively. The intensity of TENS will be set by patient`s tolerance. The total time of treatment by TENS is 20 minutes. The one MHz ultrasound with intensity of 0.8w/cm² will be used by 5 minutes.Hot pack will be used by 20 minutes.

**Category**

Rehabilitation

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Physiotherapy Department of Rehabilitation Sciences Faculty

**Full name of responsible person**

Farahnaz ghafarinejad

**Street address**

POBox: 71345-1733, Rehabilitation Sciences Faculty, Abiverdi 1 street, Chamran Blvd., Shiraz

**City**

Shiraz

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Basir Hashemi

**Street address**

Zand Blv.

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

**Name of organization / entity**

Shiraz University of Medical Sciences, Rehabilitation Sciences Faculty

**Full name of responsible person**

Sara Abolahrari Shirazi

**Position**

Physiotherapy MSc.

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## Person responsible for updating data

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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*