Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Name of organization / entity

Shiraz University of Medical Sciences- Rehabilitation Sciences Faculty

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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

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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.

Other areas of specialty/work

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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