

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of kinesiotaping of vastus medialis obliquus muscle on pain and balance in the elderly with knee osteoarthritis

Protocol summary

Study aim

Determination of the effects of kinesiotaping of vastus medialis obliquus muscle on pain and balance in the elderly with knee osteoarthritis

Design

Parallel group randomized clinical trial , double blind

Settings and conduct

Samples will be entered into the study after being informed about participation in the research and to complete the informed consent form. Then, they will be randomly divided into two groups of real and placebo kinesiotapes. They will not be known about type of received kinesiotape. Also, tapes will be installed by a therapist and evaluations will be done by another therapist. The assessor will not be aware of the type of treatment they receive.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age over 65 years; involvement to moderate knee osteoarthritis based on Kellgren and Lawrenc criteria; gain score less than 35 from Fullerton Advanced Balance Scale and less than 7 from Geriatric Depression Scale. Gain at least 24 scores from the Mini Mental Status Examination questionnaire and 3-6 from pain Visual Analogue Scale. Exclusion criteria: Neurological diseases (parkinson, stroke, neuropathy); joint replacement; vision and hearing impairment; ortho-static hypotension, dizziness and history of fall in the last 6 months; history of dislocation and fracture of the lower limb joints; history of knee, spine and ankle surgeries; history of menisci, quadriceps tendon and ligaments injuries of knee joint; allergy to kinsiotape

Intervention groups

In the intervention group, The 5-cm kinesiotape is applied to the skin along the vastus medialis obliquus muscle from the beginning to the end of the muscle (75% maximum tension). in the control group, the kinesiotape without tension is applied to the skin along the tibial crest. In the both groups intervention will take place in three sessions, with a two-day interval.

Main outcome variables

Knee pain; balance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090115001552N7**

Registration date: **2018-06-22, 1397/04/01**

Registration timing: **prospective**

Last update: **2018-06-22, 1397/04/01**

Update count: **0**

Registration date

2018-06-22, 1397/04/01

Registrant information

Name

Maryam Ebrahimian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1627 1551

Email address

ebrahimian@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-05, 1397/04/14

Expected recruitment end date

2018-11-05, 1397/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of kinesiotaping of vastus medialis obliquus muscle on pain and balance in the elderly with knee osteoarthritis

Public title
The effect of taping on pain and balance in the elderly with knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 65 years old Moderate knee osteoarthritis based on Kellgren and Lawrenc criteria approved by orthopedic surgeon or physiatrist Gain score less than 35 from Fullerton Advanced Balance (FAB) Scale Gain score less than 7 from Geriatric Depression Scale (GDS) Gain at least 24 scores from the Mini Mental Status Examination (MMSE) questionnaire Gain score 3-6 from pain Visual Analogue Scale (VAS)
Exclusion criteria:
Neurological diseases (Parkinson's disease, stroke, neuropathy, etc.) and certain orthopedic diseases such as joint replacement Having vision and hearing impairment, color blindness and ortho-static hypotension Dizziness and having a history of fall in the last 6 months History of dislocation and fracture of the lower limb joints and patella History of knee, spine and ankle surgeries History of menisci, quadriceps tendon and ligaments injuries of knee joint History of allergy to kinsiotape

Age
From **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **38**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done based on the permutation block using the Randomizer software.

Blinding (investigator's opinion)
Double blinded

Blinding description
Samples will be entered into the study after being informed about the conditions for participation in the research, how to carry out evaluations and interventions, and to complete the informed consent form. Then, they will be randomly divided into two groups of real and placebo Kinesiotapes. They will not be known about type of received Kinesiotape. Also, tapes will be installed by a therapist and evaluations will be done by another

therapist and the evaluator will not be aware of the type of treatment they receive.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Oppsite to Felestin Street, Zand Avenue

City

Shiraz

Province

Fars

Postal code

1433671348

Approval date

2018-05-08, 1397/02/18

Ethics committee reference number

IR.SUMS.REC.1397.143

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M15.4

ICD-10 code description

Erosive (osteo) arthrosis

Primary outcomes

1

Description

knee pain

Timepoint

The first session and one day after the last session of the intervention

Method of measurement

Pain Visual Analogue Scale

2

Description

Balance

Timepoint

The first session and one day after the last session of the

intervention

Method of measurement

Fullerton Advanced Balance Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The 5-cm kinesiotape is applied to the skin along the vastus medialis obliquus muscle from the beginning to the end of the muscle (with 75% maximum tension). The intervention will take place in three sessions, with a two-day interval.

Category

Rehabilitation

2

Description

Control group: The 5-cm kinesiotape without tension is applied to the skin along the tibial crest. The intervention will take place in three sessions, with a two-day interval.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz Jahandidegan Center

Full name of responsible person

Roya Razavi

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Kholdebarin Park, Shahid Beheshti Blvd.

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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

7th floor of Central Building of Shiraz University of Medical Sciences, In front of Felestin Street, Zand Avenue

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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

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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Ebrahimian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Farzaneh Moslemi Haghighi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data are shareable after samples unidentification

When the data will become available and for how long

9 months after the publication of results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

In order to compare with similar studies

From where data/document is obtainable

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What processes are involved for a request to access data/document

Applicants can request data retrieval 9 months after the publication of results, and the data will be sent after a maximum of one month.

Comments