

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of kinesio tape on knee proprioception, pain, balance and quality of life in patients with knee osteoarthritis- a double blind randomized controlled trial

Protocol summary

Study aim

Comparison of the effect of knee and quadriceps kinesio tape with sham kinesio tape on knee proprioception , pain, balance and quality of life in persons over 45 years old with knee osteoarthritis

Design

Randomized clinical trial with control group, with parallel groups, double blind, randomized, An intervention group and a control group (sham), Randomization through sealed envelopes, The sample size would have been n=22 in each groups with a 10% attrition rate.

Settings and conduct

Place the plot : Arman Shayan Rehabilitation Center This is a double-blinded randomized clinical trial. The interventions will perform by the physical therapist and the assessments and data collection will conduct by another therapist. The interventionist will aware of the groups allocation, while the patients and the outcome assessor will blind to the allocation

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with knee osteoarthritis; Knee pain history for 6 months or more; Pain score between 4 to 7 on a visual analog scale; Radiological signs in affected knee; Age \geq 45 years; Exclusion criteria : Knee joint injections within the previous 6 months; History of lower limbs fracture within the previous 6 months; Articular inflammatory diseases; Alternating swelling of the knee; History of skin allergy; History of knee soft tissue injuries or knee surrounding structures injuries; Balance disorder due to vestibular system disorders; History of knee or hip replacement; Rheumatoid arthritis; Deformity or contracture in the ankle, knee, or hip joints;

Intervention groups

1) The treatment group received 3 physiotherapy exercises and kinesio tape therapy 2) control group received the same 3 physiotherapy exercises and sham

kinesio tape

Main outcome variables

knee Joint position sense (proprioception) error, Rest pain and task pain, Balance, Quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180916041051N1**

Registration date: **2018-12-22, 1397/10/01**

Registration timing: **retrospective**

Last update: **2018-12-22, 1397/10/01**

Update count: **0**

Registration date

2018-12-22, 1397/10/01

Registrant information

Name

Shabnam Shahali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2225 8769

Email address

shahali.sh@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2018-08-01, 1397/05/10
Actual recruitment end date
2018-09-15, 1397/06/24
Trial completion date
2018-09-15, 1397/06/24

Scientific title

The effect of kinesio tape on knee proprioception, pain, balance and quality of life in patients with knee osteoarthritis- a double blind randomized controlled trial

Public title

The effect of kinesio tape on knee proprioception, pain , balance and quality of life in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with grade 2, 3 OA knee (tibiofemoral) according to kellgren-and-lawrence-system Diagnosed and referred by a specialist Pain score between 4 to 7 on a visual analog scale Radiological signs in affected knee Age > 45 years Knee range of motion: 0 to 100 degree Body mass index between 20 and 30 knee pain history for 6 months or more.

Exclusion criteria:

Using knee Kinesiotape within the previous 6 months Knee joint injections within the previous 6 months Using electrical stimulation within the previous 3 months Previous knee surgery History of lower limbs fracture within the previous 6 months Articular inflammatory diseases Alternating swelling of the knee History of skin allergy Patients with diabetic neuropathy Referral pain to the knee History of knee soft tissue structures injuries or knee surrounding structures injuries Balance disorder due to vestibular system disorders Patellofemoral pain syndrome of the affected side History of knee or hip replacement Rheumatoid arthritis Neurological diseases Deformity or contracture in the ankle, knee, or hip joints Ankle or hip joints osteoarthritis

Age

From **45 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Actual sample size reached: **47**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization procedures (computerized random numbers) will be conduct, and sequentially numbered

index cards with the random assignment will prepare by an investigator with no clinical involvement in the study. The index cards will fold and place in sealed, opaque envelopes. Then, the blind investigator will open each envelope and allocate the participants to the Kinesio taping or placebo taping group according to the selected index card.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blinded randomized clinical trial. Participants and assessor will be blind to the study groups. The interventions will perform by the physical therapist at a university research clinic, and the assessments and data collection will conduct by another therapist. The interventionist will aware of the groups allocation, while the patients and the outcome assessor will blind to the allocation

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2018-07-31, 1397/05/09

Ethics committee reference number

IR.IUMS.REC.1397.059

Health conditions studied

1

Description of health condition studied

knee Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description

knee joint position sense error (proprioception)

Timepoint

Before the intervention, 30 minutes after the first intervention session, after the fifth session, one week after the last evaluation for follow up

Method of measurement

inclinometer

2

Description

pain

Timepoint

Before the intervention, 30 minutes after the first intervention session, after the fifth session, one week after the last evaluation for follow up

Method of measurement

Visual analog scale

3

Description

Balance

Timepoint

Before the intervention, 30 minutes after the first intervention session, after the fifth session, one week after the last evaluation for follow up

Method of measurement

Berg balance test

4

Description

Quality of life

Timepoint

Before the intervention, after intervention sessions

Method of measurement

Persian version of the WOMAC questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: this group received 3 daily therapeutic exercises (three times a day with 10 repetition) plus 5 sessions kinesiotape therapy. The exercises were including: straight leg raising in supine position, knee flexion and extension in sitting position on a chair and isometric contraction of knee muscles in sitting position. Patients were trained to do the exercises at home. The kinesiotape is an adhesive linen. It has roughly the same thickness as the epidermis and its use has become increasingly popular in musculoskeletal

problems.

Category

Treatment - Other

2

Description

Control group: this group received 3 daily therapeutic exercises (three times a day with 10 repetition) plus 5 sessions placebo kinesiotape.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Arman Shayan Rehabilitation Center

Full name of responsible person

Shabnam Shahali

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences, Iran, Tehran

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 5555 5059

Email

shahali.sh@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Kazem Malekoti

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Phone

+98 21 86709

Email

alikarami11pt@yahoo.com

Grant name

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

80

Public or private sector

Private

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**

Iran University of Medical Sciences

Full name of responsible person

Shabnam shahali

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 2059

Email

shahali.sh@iums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Shabnam shahali

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 2059

Email

shahali.sh@iums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Shabnam shahali

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation Sciences, Iran University of Medical Sciences, Maddadkaran St., Shahid Nazari St., Mother Square, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1545913487

Phone

+98 21 2222 2059

Email

shahali.sh@iums.ac.ir

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