Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

The effectiveness of knee orthosis versus Kinesio tape on pain, physical function, strength and proprioception in patients with knee osteoarthritis

Protocol summary

Study aim
to evaluate the effectiveness of knee orthosis and Kinesio-tape on pain, physical function, muscle strength, and knee proprioception in patients with knee osteoarthritis

Design
The present study is a parallel group, prospective, quasi-experimental trial with blinded outcome assessors. The participants will be allocated to knee orthosis and or kinesio-tape groups through permuted block randomization at an assignment ratio of 1:1. To ensure allocation concealment, randomization codes were kept in opaque, sealed, sequentially-numbered envelopes.

Settings and conduct
Shahid Beheshti University

Participants/Inclusion and exclusion criteria
The American College of Rheumatology classification criteria, pain intensity of at least 4, Kellgren and Lawrence grade 2 or 3, Standing and walking without assistance Exclusion criteria: knee flexion contracture corticosteroid injection within the past 6 month neurological diseases systemic diseases BMI of more than 36 diabetes mellitus history of wearing knee orthoses or applying Kinesio-tape for the last 6 months Patellofemoral pain syndrome Hip and knee replacementd

Intervention groups
Group A: knee orthosis Group B: kinesio-tape

Main outcome variables
Pain intensity, WOMAC score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200315046784N1**
Registration date: **2021-10-06, 1400/07/14**
Registration timing: **prospective**
Last update: **2021-10-06, 1400/07/14**
Update count: **0**

Registration date
2021-10-06, 1400/07/14

Registrant information

Name
Fatemeh Azadinia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-10-13, 1400/07/21

Expected recruitment end date
2022-04-06, 1401/01/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effectiveness of knee orthosis versus Kinesio tape on pain, physical function, strength and proprioception in patients with knee osteoarthritis

Public title
Effectiveness of knee external support (knee orthosis and or kinesiotape) on knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
pain intensity of at least 4 Kellgren and Lawrence grade 2 or 3 the American College of Rheumatology classification criteria standing and walking without assistance age ranging from 50 to 65 years
Exclusion criteria:
knee flexion contracture corticosteroid injection within the past 6 month neurological diseases systemic diseases BMI of more than 36 diabetes mellitus history of wearing knee orthoses or applying Kinesio-tape for the last 6 months Patellofemoral pain syndrome Hip and knee replacement

Age
From **50 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
The group allocation will be performed through permuted block randomization at an assignment ratio of 1:1. For allocation concealment, the randomization codes will be kept in opaque, sealed, sequentially numbered envelopes. Sample size is estimated at 50, however, to take account of potential withdrawals, 56 patients (n=28 per group) will be recruited for the study. First, create and seal 28 treatment A envelopes and 28 treatment B envelopes. To create a block of 4, we will select 2 treatment A envelopes and 2 treatment B envelopes. We will shuffle these 4 envelopes thoroughly, and place this block of 4 in a separate pile. Then, we will prepare additional blocks of 4 until all 28 treatment A and B envelopes have been used. All additional blocks will be placed in their own individual piles. We will have 14 individual piles of shuffled blocks of 4, for example AABB, BBAA, ABBA, BAAB, ABAB, BABA.

Blinding (investigator's opinion)
Single blinded

Blinding description
The outcome assessor will be blinded to group allocation, because all dependent variables will be measured without the orthosis and or tape, and the patients will remove their knee orthosis or kinesio-taping before referring for post-intervention assessment. Furthermore, all data will be encoded to prevent bias and to blind the statistician.

Placebo
Not 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
Shahid Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2021-01-31, 1399/11/12

Ethics committee reference number
IR.IUMS.REC.1399.1157

Health conditions studied

1

Description of health condition studied
knee osteoarthritis

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
pain

Timepoint
pre-intervention, and after 4-weeks intervention

Method of measurement
Visual Analogue Scale (VAS)

2

Description
WOMAC index

Timepoint
pre-intervention, and after 4-weeks intervention

Method of measurement
overall WOMAC score

Secondary outcomes

1

Description
position sense error

Timepoint
Pre-intervention, and after 4 weeks intervention
Method of measurement
Isokinetic Machine

2

Description
threshold to detection of passive motion
Timepoint
pre-intervention, after 4-weeks intervention
Method of measurement
Isokinetic Machine

3

Description
force sense
Timepoint
Pre-intervention, and after 4-weeks intervention
Method of measurement
Isokinetic Machine

4

Description
quadriceps strength
Timepoint
Pre-intervention, and after 4-weeks intervention
Method of measurement
Isokinetic machine

5

Description
Timed Up and Go
Timepoint
Pre-intervention and after 4-weeks intervention
Method of measurement
time via chronometer

6

Description
one leg stance
Timepoint
pre-intervention, and after 4-weeks intervention
Method of measurement
time via chronometer

7

Description
balance index
Timepoint
pre-intervention, and after 4-weeks intervention
Method of measurement
Biodex Balance system

Intervention groups

1

Description
Intervention group: knee orthosis: Knee orthosis is made from an elastic/neoprene material and have lateral stays for more support. The patients will be asked to wear the knee orthosis all day long for 4 weeks.
Category
Treatment - Devices

2

Description
Intervention group: kinesiotape: three ''I'' strips will be taken and applied with a 50% to 75% tension. The base of the first strip will be applied 10 cm below the anterior superior iliac spine, and will be pulled along the course of the rectus femoris until the superior border of the patella. The base of the second ''I'' strip will be applied below the greater trochanter and the tape will be pulled along the course of the vastus lateralis until the lateral border of the patella. The base of the third strip will be applied from the middle 1/3 of the medial aspect of the thigh. The tape will be pulled along the course of vastus medialis towards the medial border of the patella. Kinesio tape will be applied once a week for 4 weeks, with 2 day off for the skin rest between applications.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Sport Sciences and Health, Shahid Beheshti University
Full name of responsible person
Fatemeh Azadinia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person

Dr. Seyed Abas Motavalian

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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
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Fatemeh Azadinia

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Orthotics and Prosthetics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information.

Study Protocol
Undecided - It is not yet known if there will be 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

Our research findings will be shared with all researchers, and practitioners. We will publish our research findings in scientific journals.

When the data will become available and for how long

All documents can be shared 1 year after article publication

To whom data/document is available

Researchers and health practitioners

Under which criteria data/document could be used

Use of data is only possible by mentioning the name and organizational affiliation of the correspond and co-author of the project and the published article

From where data/document is obtainable

Fatemeh Azadinia

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

Send email to corresponding author.

Comments