Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of mobilization and soft tissue release of the thoracic on the pain and disability in patients with Total Knee Arthroplasty due to knee Osteoarthritis

Protocol summary

Study aim
The primary aim of this study is to evaluate the effects of thoracic spine mobilization and soft tissue release techniques on pain and disability in TKA patients.

Design
This study is a randomized, parallel-group clinical trial without blinding, using centralized computerized randomization at an external site, with 15 participants per group.

Settings and conduct
This study is a randomized, parallel-controlled clinical trial conducted in a private physiotherapy clinic and a rehabilitation center. Eligible patients will provide informed consent and be assigned to one of two groups: the intervention group, receiving mobilization and soft tissue release in addition to conventional physiotherapy, or the control group, receiving only conventional physiotherapy. Treatment methods include 90 seconds of pressure for soft tissue release and 100 seconds of vertical pressure for spinal mobilization. Conventional physiotherapy consists of TENS and strengthening exercises. The study aims to evaluate the impact of these interventions on pain and disability in patients.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 50–80; Total Knee Arthroplasty (TKA); no medications affecting autonomic function; pain intensity >3; ≥6 months post-surgery; abstain from alcohol and caffeine 24 hours prior; positive Active Standing or Head Up Tilt tests. Exclusion Criteria: Dizziness; mental or cognitive issues; Red Flag conditions; prior lower extremity surgery; unstable blood pressure; previous spinal surgery or fractures; inability to walk; knee mechanical issues; tobacco or illicit drug use.

Intervention groups
Applying mobilization and soft tissue release techniques to the thoracic spine alongside conventional physiotherapy.

Main outcome variables
Pain intensity; disability levels; patient satisfaction post-surgery; anxiety levels; autonomic system function.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230212057390N4**
Registration date: **2024-10-02, 1403/07/11**
Registration timing: **prospective**

Last update: **2024-10-02, 1403/07/11**
Update count: **0**

Registration date
2024-10-02, 1403/07/11

Registrant information

Name
Majid Shahbazi

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
2024-10-22, 1403/08/01

Expected recruitment end date
2025-04-21, 1404/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of mobilization and soft tissue release of the thoracic on the pain and disability in patients with Total Knee Arthroplasty due to knee Osteoarthritis

Public title
The effect of mobilization and soft tissue release of the thoracic on the pain and disability in patients with Total Knee Arthroplasty
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged between 50 and 80 who have undergone TKA surgery due to severe knee osteoarthritis (1). The TKA surgical method must specifically involve posterior stability. No use of medications affecting the autonomic system, such as psychiatric drugs (21). Pain greater than 3 during functional activities (squatting, stair climbing, and rising from a chair). At least 6 months must have passed since surgery (20). No consumption of alcohol or caffeine for at least 24 hours before the evaluation session (21). Positive result on the Active Standing or Head-Up Tilt test in patients.
Exclusion criteria:
Patients with a history of dizziness, mental or cognitive issues, or hearing and speech disorders (20). Patients classified as Red Flag, including those with cancer, infection, or central nervous system disorders (20). History of surgery in the lower limbs, except for TKA surgery (20). Patients with unstable blood pressure (20). History of spinal surgery or fracture. Inability to walk independently. Mechanical and movement issues in the operated knee, such as patellofemoral syndrome or prosthesis dislocation. Smoking or use of any drugs (due to their impact on the autonomic system) (21).
Age
From **50 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
A randomized block allocation method with a block size of 4 will be used. All possible 4-person permutations will be listed for the two groups: A) intervention group and B) control group. The six permutations are as follows: 1-AABB, 2-ABAB, 3-BAAB, 4-BABA, 5-BBAA, and 6-ABBA. Then, using a random number table with a random starting point, 6 numbers between 1 and 6 will be randomly selected (either via software or the website randomization.com). For example, if the six random numbers obtained are 3, 5, 4, 3, 4, and 6, it means that the first four participants will be assigned according to block 3, the next four according to block 5, and so on. To conceal the allocation, a person without knowledge of the researchers' study will handle the group assignments.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Department of Physiotherapy, School of Paramedical and Rehabilitation Sciences, Shahid Kharazmi Educational Complex, Pardis University, Azadi Square, Mashhad.
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Province
Razavi Khorasan
Postal code
9177948964
Approval date
2024-07-09, 1403/04/19
Ethics committee reference number
IR.MUMS.FHMPM.REC.1403.093

Health conditions studied

1

Description of health condition studied
Damage to the sympathetic nerves
ICD-10 code
S24.6
ICD-10 code description
آسیب به اعصاب سمپاتیک پشت

Primary outcomes

1

Description
Pain intensity
Timepoint

First session and tenth session after intervention.

Method of measurement

To assess patient pain, the Visual Analogue Scale (VAS) will be used, consisting of a 10-centimeter ruler where individuals rate their pain, with 0 indicating no pain and 10 representing maximum pain (22).

2

Description

Disability levels

Timepoint

First session and tenth session after intervention.

Method of measurement

Disability levels will be evaluated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), with the validity and reliability of the Persian version confirmed by Eftekharsadat et al. in 2015 (23).

Secondary outcomes

1

Description

Disability levels

Timepoint

First session and tenth session after intervention.

Method of measurement

Disability levels will be evaluated using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), with the validity and reliability of the Persian version confirmed by Eftekharsadat et al. in 2015 (23).

2

Description

Patient satisfaction

Timepoint

First session and tenth session after intervention.

Method of measurement

Patient satisfaction post-Total Knee Arthroplasty (TKA) will be assessed using the Oxford Knee Score (OKS), whose Persian version's validity and reliability were established by Ebrahimzadeh et al. in 2014 (24).

3

Description

Anxiety levels

Timepoint

First session and tenth session after intervention.

Method of measurement

Anxiety levels will be evaluated using the Beck Anxiety Inventory (BAI), with the Persian version validated by Kaviani et al. in 2008 (25).

4

Description

The function of the autonomic system

Timepoint

First session and tenth session after intervention.

Method of measurement

The function of the autonomic system will be assessed using the Active Standing test, and if this test is negative, the Head Up Tilt test will be performed (21, 26).

Intervention groups

1

Description

Intervention group: Performing mobilization and soft tissue release techniques in the thoracic spine region in addition to conventional physiotherapy.

Category

Rehabilitation

2

Description

Control group: Conducting conventional physiotherapy.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad University of Medical Sciences.

Full name of responsible person

Majid Shahbazi

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Sponsors / Funding sources

1

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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
Mashhad 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
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Position
Assistant Professor
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
Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Correspondence with the university, along with logical reasons for the need for data and obtaining approval from the university's security office.

When the data will become available and for how long

After the publication of the article.

To whom data/document is available

Only for researchers employed in academic and scientific institutions.

Under which criteria data/document could be used

Data/documents are available for use only for research purposes under the following conditions: 1) obtaining written consent from the university; 2) non-commercial and academic use; 3) maintaining the confidentiality of personal information.

From where data/document is obtainable

To obtain data/documents, please contact the university's research office or the relevant department.

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

A request for data/documents typically follows these steps: First, the request is submitted to the university's research office, explaining the rationale for needing the data. After an initial review, the request is forwarded to the university's security office for approval regarding confidentiality and security. Finally, if the security office approves, the data is provided to the requester.

Comments