

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of 2 surgical methods of proximal tibial ostotomy (HTO) with and without medial meniscus repair in patients with varus knee deformity accompanied by medial meniscus injury and its effect on clinical outcomes of patients: A randomized clinical trial study

Protocol summary

Study aim

Determining the effectiveness of 2 surgical methods of proximal tibial ostotomy (HTO) with and without medial meniscus repair in patients with varus knee deformity accompanied by medial meniscus injury, results of patient satisfaction (KOOS)

Design

A randomized, controlled clinical trial with parallel groups on 110 patients. Sealed envelope.com software was used for block randomization.

Settings and conduct

Patients are referred to the operating room of Yahyanejad Hospital for surgery and undergo surgery by Dr. Jokar.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age <60 years Definite diagnosis of knee osteoarthritis, as determined by an orthopedic physician and grade 3 or higher (moderate and severe) according to the Kellgren and Lawrence osteoarthritis classification system (4) Knee pain and disability due to osteoarthritis that significantly interferes with occupation or active recreation Non-response to non-invasive treatments such as physiotherapy and medication for 3 months Medial meniscus tear as determined by MRI
Exclusion criteria: Narrowing of the lateral compartment cartilage space Lateral tibial subluxation >1 cm Medial tibial bone loss >2 or 3 mm Flexion contracture >15 degrees Knee flexion <90 degrees More than 20 degrees of correction required Inflammatory arthritis Significant peripheral vascular disease Pregnancy Opioid dependence Diabetes Failure to perform investigations Radiography

Intervention groups

1) Osteotomy: Biplanar proximal tibial osteotomy without medial meniscotomy 2) Osteotomy + medial meniscotomy: Biplanar proximal tibial osteotomy with

arthroscopic medial meniscotomy

Main outcome variables

Knee Injury and Osteoarthritis Outcome Score (KOOS)

General information

Reason for update

در جهت جامع تر و دقیق ترها و نتایج نیاز به بررسی چند زاویه دیگر هم بصورت ذخیره موجود بود و ما marco pacs بود که در نرم افزار تصمیم به این داده ها و تفسیر آنها گرفتیم. امیدوارم مورد تایید محترم هم قرار بگیرد.

Acronym

IRCT registration information

IRCT registration number: **IRCT20240425061571N2**

Registration date: **2025-03-13, 1403/12/23**

Registration timing: **prospective**

Last update: **2025-10-05, 1404/07/13**

Update count: **2**

Registration date

2025-03-13, 1403/12/23

Registrant information

Name

yasin sharifzadeh

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

2025-04-21, 1404/02/01

Expected recruitment end date

2026-02-20, 1404/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of 2 surgical methods of proximal tibial ostotomy (HTO) with and without medial meniscus repair in patients with varus knee deformity accompanied by medial meniscus injury and its effect on clinical outcomes of patients: A randomized clinical trial study

Public title

Comparison of 2 surgical methods of ostotomy with and without medial meniscus repair in patients with knee deformity accompanied by medial meniscus injury.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age under 60 years and Lawrence (4) Knee pain and disability due to osteoarthritis that significantly interferes with employment or active recreation Failure to respond to non-invasive treatments such as physical therapy and medication for 3 months Medial meniscus tear based on MRI

Exclusion criteria:

Narrowing of the lateral compartment cartilage space Lateral tibial subluxation of more than 1 cm Loss of bone in the inner side of the tibia of more than 2 or 3 mm Flexion contracture greater than 15 degrees Knee bending less than 90 degrees More than 20 degrees of correction required Inflammatory arthritis Significant peripheral vascular disease Pregnancy Opioid addiction Diabetes

Age

To 60 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 110

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be performed using the permutation block method. In this method, the size of each block will be 4 and the allocation ratio in each block will be 1.1. In this way, each block will have an equal number (2 of each method) of each surgery. The order of surgery will be randomly selected by the methodologist using the sealed envelope.com software. In order to conceal the treatment process, envelopes of the same shape and

size will be divided into the number of participants in the study, and the type of surgery will be written inside the envelope. Random codes will be written on the envelopes by the methodologist. When each participant enters the study, the relevant code will be recorded in the patient file. In case of severe complications, the relevant codes will be opened.

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 Babol University of Medical Sciences

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Sardar Soleimani St

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Mazandaran

Postal code

4716699118

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.MUBABOL.HRI.REC.1403.401

Health conditions studied**1****Description of health condition studied**

Osteoarthritis knee

ICD-10 code

M19.93

ICD-10 code description

Secondary osteoarthritis, unspecified site

Primary outcomes**1****Description**

Knee Injury and Osteoarthritis Outcome Score (KOOS)

Timepoint

Four initial assessments will be conducted (at the beginning of the study, after surgery, after 1 and 6 months of surgery).

Method of measurement

Knee Injury and Osteoarthritis Outcome Score (KOOS)
Questionnaire

Secondary outcomes

1

Description

Visual Analog Scale - VAS

Timepoint

Before intervention, 6 months after intervention

Method of measurement

Visual Analogue Pain Scale

2

Description

joint line convergence angle (JLCA)

Timepoint

Before intervention, 6 months after intervention

Method of measurement

by marco pacs software

3

Description

Posterior tibial slope angle

Timepoint

Before intervention, 6 months after intervention

Method of measurement

by marco pacs software

4

Description

Hip-knee-ankle (HKA) angle

Timepoint

Before intervention, 6 months after intervention

Method of measurement

three joint view x ray

Intervention groups

1

Description

Intervention group: Osteotomy technique A 6 to 8 cm longitudinal skin incision was made in the anteromedial and proximal tibia from the infrapatella to the distal. After dissection of the subcutaneous tissue, the MCL was separated from the bone and retracted posteriorly. Since the osteotomy point was 4 cm from the joint surface, there was no need to cut the pes anserinus tendons and only if necessary, a 5 mm incision was made and retracted posteriorly. The patellar tendon was identified and protected with a retractor. A 2.4 mm Kirschner wire was inserted under fluoroscopy (C-ARM Fluoroscopy) from the osteotomy entry point on the medial side of the tibia in the anterior third of the tibia, which is 4 cm distal to the joint line, towards the fibular head. The tip of the Kirschner wire was placed 1.5 cm distal to the joint line

and 1 cm medial to the lateral cortex. Another Kirschner wire is placed parallel to the previous Kirschner wire in the posterior third of the tibia. After placing 2 Kirschner wires, an osteotomy is performed with a saw, and special attention should be paid to attaching the blade to the wire, and we cut up to 1 cm medial to the lateral cortex, and the next cut is made under the tibial tuberosity at an angle of 110 degrees in a position where the hand is parallel to the ground. After completing the two cuts, we use the LAMINA SPREADER to open the osteotomy site. We open the LAMINA SPREADER opening according to the desired correction angle. Then it is fixed with a 6-hole locking plate. It should be noted that during fixation, there must be a sandbag under the patient's heel and the tip of the LAMINA SPREADER is placed in the posterior third of the tibia.

Category

Treatment - Surgery

2

Description

Intervention group: In addition to the osteotomy surgery below, the patient underwent arthroscopic partial meniscotomy. Osteotomy technique A 6 to 8 cm longitudinal skin incision was made in the anteromedial and proximal tibia from the infrapatella to the distal. After dissection of the subcutaneous tissue, the MCL was separated from the bone and retracted posteriorly. Since the osteotomy starting point was 4 cm from the joint surface, there was no need to cut the pes anserinus tendons and only if necessary, a 5 mm incision was made and retracted posteriorly. The patellar tendon was identified and protected with a retractor. A 2.4 mm Kirschner wire was inserted under fluoroscopy (C-ARM Fluoroscopy) from the osteotomy entry point on the medial side of the tibia in the anterior third of the tibia, which is 4 cm distal to the joint line, towards the fibular head. The tip of the Kirschner wire is placed 1.5 cm distal to the joint line and 1 cm medial to the lateral cortex. Another Kirschner wire is placed parallel to the previous Kirschner wire in the posterior third of the tibia. After placing 2 Kirschner wires, an osteotomy is performed with a saw, and special attention should be paid to attaching the blade to the wire, and we cut up to 1 cm medial to the lateral cortex, and the next cut is made under the tibial tuberosity at an angle of 110 degrees in a position where the hand is parallel to the ground. After completing the two cuts, we use the LAMINA SPREADER to open the osteotomy site. We open the LAMINA SPREADER opening according to the desired correction angle. Then it is fixed with a 6-hole locking plate. It should be noted that during fixation, there must be a sandbag under the patient's heel and the tip of the LAMINA SPREADER is placed in the posterior third of the tibia.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Shahid Yahya Nejad Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Yasin Sharifzadeh

Position

Orthopedic senior resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Allowed

When the data will become available and for how long

3 years after publication of the article

To whom data/document is available

Responsible

Under which criteria data/document could be used

Allowed

From where data/document is obtainable

3 years

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

Email

Comments