Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 بود که در نرم افزار marco pacs بصورت ذخیره موجود بود و ما 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

Country

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
Street address
Sardar Soleimani St
City
Babol
Province
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 ostotomy 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 ostotomy 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 ostotomy 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 ostotomy 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 ostotomy 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 ostotomy 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 ostotomy 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
Rahmatollah Jokar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
Dr. Balaghi

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balghi@yahoo.com

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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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