

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of multiple needle puncturing and subperiosteal elevation of MCL on clinical and radiographic outcomes of patients undergoing total knee arthroplasty in patients with osteoarthritis with severe varus deformity, a double-blind randomization clinical trial

Protocol summary

Study aim

The aim of our study is to evaluate the clinical and radiographic results of the knee by multiple needle puncture method compared to the subperiosteal elevation method of MCL in patients undergoing total knee arthroplasty with severe varus osteoarthritis knee.

Design

Double-Blind randomized clinical trial With a parallel design of a phase 3 study (The method of random blocks and considering 29 blocks of 6 for 174 patients into two groups of intervention and control Will be produced by the online site <https://www.sealedenvelope.com>)

Settings and conduct

In this double blind randomized clinical trial, Severe varus osteoarthritis knee patients undergoing primary total knee arthroplasty will be enrolled. Patients referred to our orthopedic academic center (Poursina hospital) after obtaining informed consent will be divided randomly to two groups of intervention (multiple needle puncturing) and control (subperiosteal elevation).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Severe varus osteoarthritis knee patients undergoing primary total knee arthroplasty, varus angle of above 15 degrees, the age group of 55 years to above, individual consent for participation in the study Exclusion criteria: Any history of knee surgery, valgus knees, bone grafting for a severe deformity or bone defect, rheumatoid arthritis, neuromuscular problems including severe spinal disease

Intervention groups

Intervention group: Multiple needle puncturing for release MCL Control group: Subperiosteal elevation for release MCL

Main outcome variables

Femorotibial angle, Knee society score (KSS), womac score, Complications of surgery (infection, hematoma,

DVT)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110809007274N18**

Registration date: **2022-05-09, 1401/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2022-05-09, 1401/02/19**

Update count: **0**

Registration date

2022-05-09, 1401/02/19

Registrant information

Name

Mohsen Mardani Kivi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1321 1470

Email address

mardani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2023-04-19, 1402/01/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of multiple needle puncturing and subperiosteal elevation of MCL on clinical and radiographic outcomes of patients undergoing total knee arthroplasty in patients with osteoarthritis with severe varus deformity, a double-blind randomization clinical trial

Public title
Effect two methods of multiple needle puncturing and subperiosteal elevation of MCL undergoing total knee arthroplasty in patients with osteoarthritis with severe varus deformity

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Severe varus osteoarthritis knee patients undergoing primary total knee arthroplasty Varus angle of above 15 degrees The age group of 55 years to above Individual consent for participation in the study
Exclusion criteria:
Any history of knee surgery Valgus knees Bone grafting for a severe deformity or bone defect Rheumatoid arthritis Neuromuscular problems, including severe spinal disease

Age
From **55 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **174**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, according to the estimated sample size, the online site <https://www.sealedenvelope.com> will be used to generate a randomization list of individuals to study groups. Based on the method of random blocks and considering 29 blocks of 6 for 174 patients into two groups of intervention and control Will be produced by the site. Eligible patients will be Randomly allocated to two groups: multiple needle puncturing(87 patients) and subperiosteal elevation (87 patients). To ensure blinding, consecutively-numbered sealed envelopes will be used during the randomization process, and the envelope pertaining to each person will be opened only after confirming the candidate's eligibility and their signing of the consent form.

Blinding (investigator's opinion)

Double blinded

Blinding description
The present study is a double-blind study and the patients under study do not know the type of surgical intervention process. The evaluator will also be an orthopedic assistant who is not present in the treatment process of these patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Guilan university of medical sciences

Street address

Guilan University of Medical Sciences' Headquarters, In front of 17 Shahrivar Hospital, Shahid Siadati St., Namjoo St., Rasht, Guilan, Iran

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Rasht

Province

Guilan

Postal code

41937-13194

Approval date

2022-04-06, 1401/01/17

Ethics committee reference number

IR.GUMS.REC.1401.008

Health conditions studied

1

Description of health condition studied

Osteoarthritis with severe varus deformity

ICD-10 code

M17.9

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Knee society score (KSS)

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

Based on KSS questionnaire

2

Description

womac score

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

Based on womac questionnaire

3

Description

Femorotibial angle

Timepoint

Before and 3 and 6 months after surgery

Method of measurement

Based on varus angle(Radiography)

4

Description

Infection

Timepoint

After surgery

Method of measurement

Wound discharge during examination

5

Description

hematoma

Timepoint

After surgery

Method of measurement

hematoma after surgery

6

Description

Deep vein thrombosis (DVT)

Timepoint

After surgery

Method of measurement

Incidence of DVT after surgery

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Multiple needle puncturing for release MCL underwent total knee arthroplasty in patients with osteoarthritis with severe varus deformity

Category

Treatment - Surgery

2

Description

Control group: Subperiosteal elevation for release MCL

underwent total knee arthroplasty in patients with osteoarthritis with severe varus deformity

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina Hospital

Full name of responsible person

dr. Mohsen Mardani-kivi

Street address

Poursina Hospital, Poursina Crossroads, Rasht, Guilan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

dr. Mohammadreza Naghipour

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

dr. Mohsen Mardani-kivi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Zohre Darabipour

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Researcher

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Master

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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

No - There is not a plan to make this available