Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Investigation and comparison of the results of correction of knee varus deformity with medial open wedge and lateral closed wedge in patients with symptomatic genu varum

Protocol summary

Study aim

Investigation and comparison of the results of correction of knee varus deformity with medial open wedge and lateral closed wedge

Design

In this study, sample size is 76 and no blinding is done. A random number is selected from the random numbers table and placed in sealed envelopes

Settings and conduct

This clinical trial study will investigate and compare two methods of varus deformity correction. Considering the sample size qualified patients are introduced to Ghaem and Mehr hospitals of Mashhad, after informed consent, based on the random numbers table and the prepared envelope, an envelope is opened and the patient is assigned to one of the surgery groups. Before surgery, a checklist including patient's demographic information and life quality and satisfaction questionnaire, as well as radiology information for each patient will be completed. After surgery, the patient will be evaluated in terms of short-term and long-term outcomes as well as complications of the surgery and changes related to patient's satisfaction are assessed at intervals of 6 weeks, 3 months, 6 months and one year

Participants/Inclusion and exclusion criteria

Inclusion criteria :having significant pain and disability due to osteoarthritis; varus deformity; patient's ability to use crutch after operation; good vascular status. Exclusion criteria: history of internal disease; history of fracture in the lower extremity; history of surgery in the knee joint; lower limb muscular lesion; heart failure and varicosis

Intervention groups

Intervention group one: Deformity treatment of the knee with medial open wedge method Intervention group two: Deformity treatment of the knee with lateral closed wedge method

Main outcome variables

Pain measurement using VAS; investigation of knee Injury and osteoarthritis outcome score (KOOS); range of motion and stability of medial and lateral ligaments.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180408039241N1**
Registration date: **2019-01-20, 1397/10/30**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-20, 1397/10/30**
Update count: **0**

Registration date

2019-01-20, 1397/10/30

Registrant information

Name

Hadi Makhmalbaf

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-26, 1397/07/04

Expected recruitment end date

2019-12-25, 1398/10/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation and comparison of the results of correction of knee varus deformity with medial open wedge and lateral closed wedge in patients with symptomatic genu varum

Public title

Investigation of the results of correction of knee varus deformity with two surgical methods in patients with bow legs

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having significant pain and disability in respect to osteoarthritis Varus deformity Patient's ability to use crutch after operation Good vascular status

Exclusion criteria:

History of internal disease History of fracture in the lower extremity History of surgery in the knee joint Having muscular lesion in the lower extremity Heart failure and varicosis

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups. For each group, 38 random numbers are selected from random numbers table and placed in sealed envelopes. Envelopes are given to a specific person, and when a patient refers for surgery, an envelope is opened and based on it, the patient is placed in a specific group.

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

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Approval date

2018-05-30, 1397/03/09

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.451

Health conditions studied

1

Description of health condition studied

Genuvarum

ICD-10 code

M21.1

ICD-10 code description

Varus deformity, not elsewhere classified

Primary outcomes

1

Description

Measuring the amount of pain

Timepoint

Before surgery and 6 months and one year after surgery

Method of measurement

Using the pain rate questionnaire (Visual Analogue Scale)

2

Description

Knee injuries

Timepoint

Before surgery and 6 months and one year after surgery

Method of measurement

Using a simple graph of knee and questionnaire of knee Injury and osteoarthritis outcome score (KOOS)

3

Description

Knee joint range of motion

Timepoint

before surgery and at intervals of 2 weeks, 6 weeks, 3 months, 6 months and one year after surgery

Method of measurement

Clinical examinations

4

Description
Stability of medial and lateral ligaments
Timepoint
2 weeks, 6 weeks, 3 months, 6 months and one year after surgery
Method of measurement
Clinical examinations

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, patients are treated with medial opening wedge osteotomy. Under sterile condition and general anesthesia, incision of medial proximal tibia is carried out and the proximal tibia becomes exposed. Afterwards, on the tibial tuberosity surface, medial proximal osteotomy is carried out and a wedge with appropriate size is placed in location of osteotomy and is fixed using proximal tibia t-plate, 3 proximal and 3 distal screws. Then, drain placement will be done
Category
Treatment - Surgery

2

Description
Intervention group 2: In this group, patients are treated by lateral closing wedge osteotomy. Under sterile condition and general anesthesia, incision of lateral and proximal tibia is performed. Osteotomy of the head of fibula is carried out while maintaining peroneal nerve. Afterwards, corticotomy of interior tibia with maintaining patellar tendon , corticotomy of medial tibia with maintaining MCL (medial collateral ligament), lateral corticotomy with maintaining LCL (lateral collateral ligament) and posterior corticotomy with maintaining popliteal artery are carried out. Lateral wedge correction is performed using 2 genu varum staples.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Ali Dastjerdi
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2

Recruitment center
Name of recruitment center
Mehr Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
960409
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
Mashhad University of Medical Sciences
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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
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
All data can be shared after patients are made unidentifiable.
When the data will become available and for how long
Data can be accessible 6 months after results are published.
To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.
Under which criteria data/document could be used
Carrying out analysis on data is permitted.
From where data/document is obtainable
Data can be accessible through sending an email to the corresponding author.
What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments