Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Assessment the effect of high tibial osteotomy (HTO) surgery on the analysis of gate parameters of patients referred to Imam Hossein Hospital between 1400 and 1402.

Protocol summary

Study aim

Determining the effect of high tibial osteotomy (HTO) surgery on the analysis of gate parameters of patients referred to Imam Hossein Hospital

Design

Clinical trial with control group, with parallel groups, randomized, phase 2 on 15 patients. The rand function of Excel software was used for randomization.

Settings and conduct

Before surgery, the patients referred to Imam Hossein Hospital were subjected to gait analysis using a motion analysis device, then tibial osteotomy (HTO) surgery will be performed and within 6 months after the surgery and when The patients should be able to walk and the tibia completely fused. Again, they were subjected to gait analysis using the motion analysis device, then the information was collected and compared using the checklist filled before and after the operation. It will be analyzed using descriptive and average statistical methods and chi-square statistical test, Fisher's exact test, paired t-test and independent t-test.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pain and disability caused by osteoarthritis, Evidence of arthritis changes limited to a one compartment in the knee and Exiteria criteria: Bone loss in the medial compartment is more than 2-3 mm, F.C > 15° Knee flexion <90° , The need to correct alignment more than 20° , Inflammatory arthritis, Symptomatic peripheral vascular diseases, Lateral Tibia subluxation > 1cm.

Intervention groups

Single group study. Intervention: High tibial osteotomy (HTO) surgery.

Main outcome variables

The length of a step; The duration of one step; Number of steps; Step speed

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20230725058922N1**
Registration date: **2023-12-12, 1402/09/21**
Registration timing: **prospective**

Last update: **2023-12-12, 1402/09/21**
Update count: **0**

Registration date

2023-12-12, 1402/09/21

Registrant information

Name

Ali Saeed

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment the effect of high tibial osteotomy (HTO) surgery on the analysis of gate parameters of patients referred to Imam Hossein Hospital between 1400 and 1402.

Public title
Assessment the effect of high tibial osteotomy (HTO) surgery on the of gate

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Pain and disability caused by osteoarthritis Evidence of arthritis changes limited to a one compartment in the knee
Exclusion criteria:
Bone loss in the medial compartment is more than 2-3 mm F.C > 15° Knee flexion <90° The need to correct alignment more than 20° Inflammatory arthritis Symptomatic peripheral vascular diseases Lateral Tibia subluxation > 1cm

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **2**
Before surgery and six months after surgery

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
Do not have

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University of Medical Sciences
Street address
Shahid Beshti university of medical sciences,Aarabi st,Daneshjo blvd,Valenjak,Tehran
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Tehran
Province
Tehran
Postal code
1985717443

Approval date
2023-07-01, 1402/04/10

Ethics committee reference number
IR.SBMU.MSP.REC.1402.135

Health conditions studied

1

Description of health condition studied
Genu Varum and GenuValgum

ICD-10 code
1.Q74

ICD-10 code description
Congenital malformation of knee

Primary outcomes

1

Description
Gate before and after surgery

Timepoint
Before surgery and six months after surgery

Method of measurement
Measurement by gate analysis parameters: step length, step speed, number of steps per minute, duration

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: High tibial osteotomy (HTO) surgery. Six months after the surgery, the patient goes to measure the gate by the parameters of the gate analysis and the results are obtained

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein hospital
Full name of responsible person
Doctor Mohammad Mahdi Omidian

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
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Position
Assistant Professor
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
-
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available