

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Assessment the effect of high tibial osteotomy (HTO) surgery on the analysis of gait 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 gait 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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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

City

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Province

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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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Imam Hossein Hospital ; Madani Ave ; Tehran Town

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Full name of responsible person

Dr. Mohammad Mehdi Omidian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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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