

# 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)

##### Phone

+98 21 3378 3049

##### Email address

ali.saeed1410@gmail.com

##### 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

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

**Street address**

Imam Hossein Hospital ; Madani Ave ; Tehran Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

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**Fax****Email**

info@ehmc.ir

**Web page address**

<https://ehmc.sbm.ac.ir>

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Doctor Mohammad Mahdi Omidian

**Street address**

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**Web page address**

<https://sbmu.ac.ir>

**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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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Assistant Professor

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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