

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A Finit Element Study of Stress Distribution in Varus Knee-before and after high tibia osteotomy

Protocol summary

Summary

A-Patients selection :cases are selected among patients referred to knee clinic of shafa yahyaian hospital according to inclusion criteria:1.age:20-35 yrs 2.sex:male 3.femur and tibia anatomic axis difference <0deg 4.No meniscal or ligament injury 5.No chondral lesion 6.No ligament laxity 8.No bony or systemic diseases9.Normal BMI(18-25) 9.No anatomic or mechanical axis disorders in lower limb except for genovarum B-Radiologic assessment:1.Xray:AP,lateral,patella view,alignment view 2.knee MRI 3.knee CT scan(3D with reconstruction) 4.stance phase dynamic fluoroscopy of knee C-computerized modeling and finit element study:after transferring data to a specific computer with use of simpleware software ,finit element study of stress distribution in compartments of knee will be done. D-High tibia osteotomy:open wedge high tibia osteotomy with preservation of lateral cortex hing and iliac crest auto bone graft will be done. E-Radiologic assessment 6 month after surgery: after complete union of osteotomy site and complete rehabilitation and return to pre operative level of function and normal gait pattern,radiologic assessment in section B will be done. F-Computerized modeling and finit element study G-The results in section C and section F will be compared and discussed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109037464N1**
Registration date: **2012-05-08, 1391/02/19**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-05-08, 1391/02/19

Registrant information

Name

Mohammad Ali Enayatollahi

Name of organization / entity

Shafa Yahyaian Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 3354 2001

Email address

m-jabalameli@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran Univercity of Medical Sciences

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2012-03-19, 1390/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Finit Element Study of Stress Distribution in Varus Knee-before and after high tibia osteotomy

Public title

A Finit Element Study of Stress Distribution in Varus Knee -before and after high tibia osteotomy

Purpose

Health service research

Inclusion/Exclusion criteria

1.age:20-35 yrs 2.sex:male 3.femur and tibia anatomic axis difference <0deg 4.No meniscal or ligament injury

5.No chondral lesion 6.No ligament laxity 8.No bony or systemic diseases9.Normal BMI(18-25) 9.No anatomic or mechanical axis disorders in lower limb except for genuvarum

Age

From **20 years** old to **35 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **2**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

tehran university of medical science

Street address

6th floor general university organization ,ghods st.keshavarz blvd.

City

tehran

Postal code

Approval date

2011-10-16, 1390/07/24

Ethics committee reference number

90/130/1442/ص

Health conditions studied

1

Description of health condition studied

genuvarum

ICD-10 code

M21.1(6)

ICD-10 code description

varus deformity,not elsewhere classified

Primary outcomes

1

Description

knee stress distribution

Timepoint

before and 6 month after high tibia osteotomy

Method of measurement

finite element study with use of simpleware software

Secondary outcomes

1

Description

genuvarus correction

Timepoint

6 month after high tibia osteotomy

Method of measurement

X-ray:alignment view

Intervention groups

1

Description

High tibia osteotomy

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

shafa yahyaian hospital

Full name of responsible person

mohammad ali enayatollahi

Street address

baharestan sq. tehran

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

tehran university of medical science

Full name of responsible person

doctor fotuhi

Street address

6th floor,central university organization,ghods st. keshavarz blvd.

City

tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

tehran university of medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

tehran university of medical science

Full name of responsible person

mohammad ali enayatollahi

Position

orthopedic surgeon

Other areas of specialty/work**Street address**

shafa yahyaian hospital,baharestan sq.

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Postal code**Phone**

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jabalameli@sina.tums.ac.irenayatollahi_md@yahoo.com

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

tehran university of medical science

Full name of responsible person

mahmood jabalameli

Position

professor of orthopedics

Other areas of specialty/work**Street address**

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m-jabalameli@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

tehran universiyu of medical science

Full name of responsible person

mohammad ali enayatollahi

Position

orthopedic surgeon

Other areas of specialty/work**Street address**

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enayatollahi-md@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty