Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 genovarum

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 gentral 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

finit 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

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

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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
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
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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