

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparsion of uniplan versus bipaln distal femur osteotomy with or whitout bone graft

Protocol summary

Study aim

Comparison of biplane and uniplane methods in distal femur osteotomy

Design

A randomized clinical trial, by lottery method (selection from pre-prepared sealed envelopes), with four parallel groups, sample size 68 patients, one-sided blind (patients).

Settings and conduct

Ba'ath Hospital and Bu Ali Hospital, Hamedan

Participants/Inclusion and exclusion criteria

Inclusion criteria: People between 18 and 45 years old, with valgus deformity, valgus angle more than 12 degrees, with pain, the slope of the articular surface is more than 10 degrees from the horizon, low space of joint surface in lateral or medial knee. Exclusion criteria: History of distal femur fracture, history of skin diseases such as psoriasis, history of systemic and genetic diseases related to bone deformity.

Intervention groups

1- Distal femur osteotomy by biplane method with bone graft 2- Distal femur osteotomy by monoplane method with bone graft 3- Distal femur osteotomy by (biplane or monoplane method) without bone graft

Main outcome variables

Union time; patients' knee functional score using KSS questionnaire; satisfaction rate using SSQ-8 questionnaire; valgus angle using mLDFA measurement.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211208053330N1**

Registration date: **2023-10-01, 1402/07/09**

Registration timing: **retrospective**

Last update: **2023-10-01, 1402/07/09**

Update count: **0**

Registration date

2023-10-01, 1402/07/09

Registrant information

Name

Sadegh Abedi

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

2021-05-05, 1400/02/15

Actual recruitment end date

2022-08-23, 1401/06/01

Trial completion date

2023-08-23, 1402/06/01

Scientific title

Comparsion of uniplan versus bipaln distal femur osteotomy with or whitout bone graft

Public title

Comparsion of uniplan versus bipaln distal femur osteotomy with or whitout bone graft

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Varus or valgus angle more than 12 degrees with pain The slope of the articular surface is more than 10 degrees from the horizon low space of the joint surface in the lateral or medial knee Exclusion criteria: History of distal femur fracture History of skin diseases such as psoriasis History of systemic and genetic diseases related to bone deformity	Education unit, Besat hospital, Motahari Ave, Hokama Blvd, Hamedan
Age From 18 years old to 45 years old	City Hamedan
Gender Both	Province Hamadan
Phase N/A	Postal code 4541165148
Groups that have been masked • Participant • Outcome assessor • Data analyser	Approval date 2023-05-03, 1402/02/13
Sample size Target sample size: 68 Actual sample size reached: 68	Ethics committee reference number IR.UMSHA.REC.1402.092
Randomization (investigator's opinion) Randomized	Health conditions studied
Randomization description Randomization will be done in a simple way with an individual unit, and using a sealed envelope that has already been poured into the basket in equal numbers. Patients are unaware of the treatment method. But the surgeon knows the procedure. But after that, the information is recorded in the form of code and the person analyzing the information does not know the type of methods	1 Description of health condition studied Genu Valgum ICD-10 code ICD-10 code description
Blinding (investigator's opinion) Single blinded	Primary outcomes
Blinding description The participants will not know about the surgery procedure. Because the methods in radiology are the same, and the cost and equipment used or the type of surgical incision are the same. Your information is recorded as a code and the analyzer will analyze only 4 groups without specific names.	1 Description Union time Timepoint 3 months - 6 months - 1 year Method of measurement Complete union in control X-ray
Placebo Not used	Secondary outcomes
Assignment Parallel	1 Description KSS sore Timepoint 1 year Method of measurement Knee Society Score
Other design features	2 Description surgical satisfaction (SSQ-8) Timepoint 12 month Method of measurement surgical satisfaction Questionnaire (SSQ-8)
Secondary Ids empty	3 Description knee valgus degree Timepoint before intervention and 3month after surgery Method of measurement mLDFA (mechanichal latral distal femoral angle) lower limb 3 joint X-ray
Ethics committees	
1 Ethics committee Name of ethics committee Ethics committee of Hamedan University of Medical Sciences Street address	

Intervention groups

1

Description

1st Intervention group: Distal femur osteotomy biplan with bone graft

Category

Treatment - Surgery

2

Description

2nd Intervention group: Distal femur osteotomy uniplan with bone graft (bone chips)

Category

Treatment - Surgery

3

Description

Control group: Distal femur osteotomy biplan or uniplan with out bone graft (bone chips)

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Besat hospital

Full name of responsible person

Sadegh Abedi

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Hokama

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Gholamreza Ghorbani

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32659875

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Grant name

Grant code / Reference number

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

No

Title of funding source

gholamreza ghorbani

Proportion provided by this source

1

Public or private sector

Private

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

Hamedan University of Medical Sciences

Full name of responsible person

Sadegh Abedi

Position

Orthopedic resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The information cannot be presented individually and one by one, and the information related to the main outcome can be shared

When the data will become available and for how long

1 month after the publication of the article

To whom data/document is available

Surgeon, researcher and analysis team

Under which criteria data/document could be used

Nameless patient information can be provided in the form of code to scientific journals or related people

From where data/document is obtainable

sadegh abedi 09901737302 drp.abedi@gmail.com

What processes are involved for a request to access data/document

Submitting a request via email and providing personal details and reasons for the request

Comments