

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The Effect of Intramedullary vs Extramedullary Tibial Guides on the Alignment of Lower Extremity following Total Knee Arthroplasty (TKA): randomized clinical trial

Protocol summary

Study aim

We will aim to compare the accuracy of IM (IntraMedullary) and EM (ExtraMedullary) techniques in providing neutral lower extremity alignment in patients undergoing TKA.

Design

The randomized, parallel clinical trial study will be performed with double blind design (patients and outcome assessor). 70 patients will be allocated into 2 groups using either Intramedullary or Extramedullary tibial guide in TKA surgery. Randomization will be performed by the four-block technique.

Settings and conduct

This study will be run in the Imam Khomeini Hospital. All patients will be allocated into 2 groups (Intramedullary and Extramedullary). Patient and assessor who will gather the data will be blinded about the type of treatment modality (Double-Blind)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Primary Total Knee Arthroplasty; Primary Knee osteoarthritis. Exclusion criteria: The patients with Major Commodities (Heart failure, CVA, DM, MI,...); Revision Total knee Arthroplasty; Uni-compartmental Knee Arthroplasty (UKA); The knee osteoarthritis due to Trauma, Hemophilia, Septic Arthritis, Inflammatory Diseases such as RA, SLE, and other Rheumatologic diseases; BMI more than 40; The patients with knee Valgus Deformity

Intervention groups

Group 1: intramedullary tibial guide. Group 2: extramedullary tibial guide.

Main outcome variables

lateral distal femoral angle (LDFA), medial proximal tibial angle (MPTA), mechanical femoral mechanical tibial or Varus angle (MFMTA or VA), joint line convergence angle (JLCA), knee society score (KSS), functional knee society score (fKSS), pain visual analog scale (VAS), knee range

of motion (ROM)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160809029286N5**

Registration date: **2020-04-21, 1399/02/02**

Registration timing: **retrospective**

Last update: **2020-04-21, 1399/02/02**

Update count: **0**

Registration date

2020-04-21, 1399/02/02

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-01, 1397/06/10

Expected recruitment end date

2019-05-01, 1398/02/11

Actual recruitment start date

2018-09-01, 1397/06/10

Actual recruitment end date

2019-05-01, 1398/02/11

Trial completion date

2019-05-01, 1398/02/11

Scientific title

The Effect of Intramedullary vs Extramedullary Tibial Guides on the Alignment of Lower Extremity following Total Knee Arthroplasty (TKA): randomized clinical trial

Public title

The comparison between Intramedullary and Extramedullary tibial guides on preserving lower limb length in TKA patients.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Primary Total Knee Arthroplasty Primary Knee osteoarthritis

Exclusion criteria:

The patients with Major Comorbidities (Heart failure, CVA, DM, MI,...) Revision Total knee Arthroplasty Unicompartement Knee Arthroplasty The knee osteoarthritis due to Trauma, Hemophilia, Septic Arthritis, Inflammatory Diseases such as RA, SLE, and other rheumatologic diseases BMI more than 40 The patients with knee Valgus Deformity

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **70**

More than 1 sample in each individual

Number of samples in each individual: **35**

The sample size will be calculated based on the study by chin et al (2005, The Journal of Arthroplasty) that compared Intramedullary (IM)and Extramedullary (EM) tibial guide in the patients who underwent TKA. we will use the rate ofpostoperative MPTA angle outlier (43.34 % vs 13.34 %) as a reference value for sample sizecalculation and we will consider the β value of 20% and α of 5%. Therefore, the calculation will result in 35 patients in each group and 70 patients in total
Actual sample size reached: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the permuted balanced blocks method will be used. In this method, six balanced blocks (1 to 6) are defined regarding the two interventions of the study (A, B) including AABB, BBAA, ABAB, BABA, ABBA, and BAAB. The patients are divided into 21 groups of four patients. The patients' numbers are inserted from 1 to 84 in a column using MS Excel software. In another column, the group of each patient is inserted, for

example: patients 1 to 4 as group 1, patients 5 to 8 as group 2, ..., patients 81 to 84 as group 21. In another Excel sheath, the groups are inserted from 1 to 21, and the blocks are inserted across each group from 1 to 6 in order till the end. In the next column, non-repeated random numbers are inserted using the "RANDL()" command. Subsequently, the order of the blocks is randomly changed. According to the block assigned with each group, the intervention regarding each patient is determined. For example, if group 1 is assigned with "AABB", the interventions will be as follows: Patient 1, A; Patient 2, A; Patient 3, B; Patient 3, B.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and assessor who will gather the data, will be blinded about the type of treatment modality (Double-Blind).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical science- Imam khomeini hospital

Street address

Ethics committee, Imam Khomeini complex Hospital(Tehran university of Medical Science) , keshavarz Blvd, Tehran

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Province

Tehran

Postal code

1419733141

Approval date

2017-07-15, 1396/04/24

Ethics committee reference number

IR.TUMS.VCR.REC.1396.2879

Health conditions studied**1****Description of health condition studied**

lower Limb alignment following TKA

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Range of Motion

Timepoint

Pre-op, 3 month , last Post-op

Method of measurement

Goniometer

2

Description

Knee Society Score

Timepoint

Pre-op, 3 month , last Post-op

Method of measurement

Knee Society Scoring (0-100)

3

Description

Knee Society Functional Score

Timepoint

Pre-op, 3 month , last Post-op

Method of measurement

Knee Society Functional Scoring (0-100)

4

Description

Pain

Timepoint

Pre-op, 3 month , last Post-op

Method of measurement

VAS (visual analog scale) 1-10

5

Description

lateral distal femoral angle (LDFA)

Timepoint

Pre-op, 3 month Post-op

Method of measurement

With 3 joint alignment view x-ray will be calculated by MediCAD software

6

Description

medial proximal tibial angle (MPTA)

Timepoint

Pre-op, 3 month Post-op

Method of measurement

With 3 joint alignment view x-ray will be calculated by MediCAD software

7

Description

mechanical femoral mechanical tibial or Varus angle (MFMTA or VA)

Timepoint

Pre-op, 3 month Post-op

Method of measurement

With 3 joint alignment view x-ray will be calculated by MediCAD software

8

Description

joint line convergence angle (JLCA)

Timepoint

Pre-op, 3 month Post-op

Method of measurement

With 3 joint alignment view x-ray will be calculated by MediCAD software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group no. 1. : Intramedullary tibial guide. The Intramedullary tibial guide in TKA surgery will be the first intervention. In total knee arthroplasty for insertion of tibial component of prosthesis, we will need a tibial guide to achieve the neutral alignment of lower limb. There are two standard method in achieving the alignment including intramedullary (Tibial intramedullary guide nail) and Extramedullary guides. The Intramedullary method uses the tibial canal and anatomical axis in achieving true lower limb alignment. This standard method is more accurate especially in high BMI patients but has some complication in the patients with tibial deformity such as perioperative fractures.

Category

Treatment - Surgery

2

Description

Intervention group no. 2. : Extramedullary tibial guide. The Extramedullary tibial guide in TKA surgery will be the Second intervention. In total knee arthroplasty for insertion of tibial component of prosthesis, we need a tibial guide to achieve the neutral alignment of lower limb. There are two standard methods in achieving the alignment including intramedullary (Tibial intramedullary guide nail) and Extramedullary guides. The Extramedullary method uses the tibial shaft and metatarsi bone 2 as a guide in achieving true lower limb alignment. This standard method is faster and easier without complication but there is controversy in accuracy of Extramedullary

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Complex Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

-

Proportion provided by this source

100

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**

Tehran University of Medical Sciences

Full name of responsible person

Alireza Moharrami

Position

Orthopaedic Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The Effect of Intra- vs. Extramedullary Tibial Guides on
the Alignment of Lower Extremity following Total Knee
Arthroplasty

When the data will become available and for how long

January 2021

To whom data/document is available

MD

Under which criteria data/document could be used

not any more conditions

From where data/document is obtainable

Email : a.moharramy@gmail.com

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

In two weeks

Comments