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 randomize , 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 Praimary Knee osteoarthritis
Exclusion criteria:
The patients with Major Comorbidities (Heart failure, CVA, DM, MI,...) Revision Total knee Arthroplasty Unicompartment 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 size
Target 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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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
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

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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

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Medical doctor

Other areas of specialty/work
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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