Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of amount of bone cement penetration and short-term outcomes in total knee arthroplasty with and without the use of tourniquets

Protocol summary

Study aim

Determining the average amount of bleeding, the amount of pain, the strength of knee extension and flexion, the number of changes in body size, and the incidence of complications after the operation, comparing the amount of knee ROM changes in total knee arthroplasty in two methods with and without the use of a tourniquet. Comparison of the amount of cement penetration in total knee arthroplasty in two methods with and without Using a tourniquet Investigating the relationship between BMD score and cement penetration rate in patients undergoing total knee joint surgery

Design

A clinical trial with a control group, with a parallel-group, double-blind, on 60 patients who are randomized by randomization.com

Settings and conduct

The study is conducted on patients referred to the Imam Khomeini Orthopedic Clinic in Tehran who are candidates for TKA. The surgeon, the patients, and the data analyst are blinded, which is done by the secretary of the blinding and randomization of the patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria Diagnosis and confirmation of indications for TKA Age 55 to 85 years BMI below 45 kg/m2 Kellgren & Lawrence osteoarthritis with score III ASA score I or II NexGen Zimmer Biomet and DePuy implants exclusion criteria History of previous knee fracture or surgery malignancy Rheumatoid disease Cardiovascular disease infectious disease Neurological disorder Liver failure DVT/PTE/Glucocorticoid,heparin,warfarin/neuromuscular disease

Intervention groups

The first group includes patients who undergo surgery with the use of a tourniquet, and the second group includes patients who undergo surgery without the use of a tourniquet.

Main outcome variables

The results of the study include reduction of pain, bleeding, postoperative complications, increase of muscle strength, increase of knee ROM, increase of cement penetration after TKA operation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221116056519N1**
Registration date: **2022-12-18, 1401/09/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-18, 1401/09/27**
Update count: **0**

Registration date

2022-12-18, 1401/09/27

Registrant information

Name

Hesan Rezaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2169 2614

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hesan.rezaee@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-29, 1401/09/08

Expected recruitment end date

2023-05-09, 1402/02/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of amount of bone cement penetration and short-term outcomes in total knee arthroplasty with and without the use of tourniquets

Public title

Tourniquet effects on knee joint replacement

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis and confirmation of indications for total knee arthroplasty surgery 55 to 85 years old BMI < 45 osteoarthritis with 3 score in kellgren and lawrence ASA score 1 or 2 TKA with Nextgen Zimmer Biomet or DePuy prosthesis primary TKA

Exclusion criteria:

previous knee fracture or surgery malignancy rheumatoid diseases cardiovascular diseases infectious diseases neurologic diseases hepatic failure disease coagulopathy disorders glucocorticoid or heparin or warfarin consumption previous history of DVT or PTE neuromuscular diseases

Age

From **55 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by the method of 2 blocks and individually by the site randomization.com, done by a person outside the study and informed to the operating room personnel without the surgeon's knowledge.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization is done by a third person outside the study, and on the day of the surgery, another person outside the surgery, who is from the operating room staff, is informed, and the data is performed by another third party. It is collected without the knowledge of the surgeon. Data analysis is done by another person who is outside the study in 2 separate groups without knowing the type of intervention. At the beginning of the study, the type of intervention was explained to all patients, and consent was obtained, but the patient was unaware of the type of randomization.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

imam khomeini hospital,doctor gharib street,keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2022-07-19, 1401/04/28

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.113

Health conditions studied

1

Description of health condition studied

The amount of cement penetration, the amount of bleeding after surgery, pain after surgery, the function of muscles around the knee after surgery, the amount of knee ROM after surgery, the relationship between BMD and cement penetration in TKA

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Comparing the amount of cement penetration around the prosthesis in patients who undergo TKA surgery with and without the use of a tourniquet.

Timepoint

60 days after surgery, AP and LAT radiographs of the knee were taken, and based on the criteria of the Knee

Society Radiographic Evaluation System, cement penetration was calculated in millimeters.

Method of measurement

According to the Knee Society Radiographic Evaluation System in AP/Lat radiographs of the knee

Secondary outcomes

1

Description

Hemoglobin reduction rate after surgery

Timepoint

Hemoglobin level is measured before surgery and then on days 1, 7, 14, 60

Method of measurement

Based on cbc test and in gr/dl

2

Description

Body size changes

Timepoint

It is measured before surgery and then on days 1, 7, 14, 60

Method of measurement

In 2 places, 5 cm above the medial malleolus and 10 cm above the superior patella, the limb circumference is measured.

3

Description

knee range of motion

Timepoint

It is measured before surgery and then on days 1, 7, 14, 60

Method of measurement

in degrees and using goniometr

4

Description

knee pain

Timepoint

It is measured before surgery and then on days 1, 7, 14, 60

Method of measurement

Based on the Visual Analogue Scale

5

Description

Strength of knee extensor and flexor muscles

Timepoint

It is measured before surgery and then on days 1, 7, 14, 60

Method of measurement

Clinical examination of muscle strength

6

Description

post operation complications

Timepoint

Day 1,7,14,60

Method of measurement

Presence or absence of dvt/pte/bleeding/infection

Intervention groups

1

Description

Intervention group: patients who do not use a tourniquet to perform TKA. ZIMMER and DEPUY prostheses are used. Patients are examined for muscle strength, knee joint range of motion, and bone density measurements. Check HB.

Category

Treatment - Surgery

2

Description

Control group: patients who use a tourniquet to perform TKA. ZIMMER and DEPUY prostheses are used. Patients are examined for muscle strength, knee joint range of motion, and bone density measurements. They are also subjected to a CBC test. Check HB.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital

Full name of responsible person

Mohammad Ayati firouzabadi

Street address

Imam khomeini hospital, Doctor gharib Street, Keshavarz Blvd

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imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nima Rezaee

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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 Sciences

Proportion provided by this source
100

Public or private sector
Public

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

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

After de-identifying people, the entire data can be shared and published as a file

When the data will become available and for how long

The access period starts 9 months after the results are published

To whom data/document is available

People working in academic and scientific centers will have access to the file

Under which criteria data/document could be used

The data are for designing future studies and are allowed to be used

From where data/document is obtainable

hesan rezaee 00989128651586
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What processes are involved for a request to access data/document

Along with the request, a summary of the academic and professional degree and the university center where the student is employed should be sent. The data file will be sent within 2 weeks at most.

Comments