

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Evaluating The Results Of Addition Of Betamethasone To Multimodal Cocktail Periarticular Injection In Bilateral Total Knee Arthroplasty

Protocol summary

Study aim

Investigating the results of adding betamethasone to multiple drug injections around a joint in pain score, range of motion, satisfaction with pain relief, and postoperative complications; Also check the age, sex and weight of patients.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 and 3 on both knees of 30 patients. 4 blocks were used to randomize.

Settings and conduct

The study is to examine pain relief after joint replacement surgery at Khatam Hospital in Shahroud. Divide patients into 2 groups A and B with 4 blocks. A cocktail containing betamethasone is injected in group A on the right foot and in group B on the left foot. Patients, researchers, physiotherapists, and all nursing staff are unaware of these groupings.

Participants/Inclusion and exclusion criteria

People between the ages of 50 and 90 with advanced osteoarthritis, which is a candidate for bilateral knee replacement enter. Contraindications to the use of the studied drugs (including known allergies or intolerance to one of the drugs, fungal infections, heart, liver, brain, kidney and inflammatory diseases of the joints, people with bleeding disorders, gastrointestinal bleeding, Asthma, glaucoma, cataracts and diabetics), patients weighing more than 100 kg, patients with neuropathic pain and sensory disturbances in the legs, people with a history of knee surgery are excluded from the study.

Intervention groups

In a group of patients, a cocktail containing betamethasone (betamethasone, Tranexamic acid, bupivacaine and ketorolac) is injected into the right knee, and a betamethasone-free cocktail (Tranexamic acid, bupivacaine and ketorolac) is injected into the left knee; In the other group, the opposite is true.

Main outcome variables

Pain score; Knee range of motion; Oxford pain score;

Patients' satisfaction with pain relief; Wound complications

General information

Reason for update

Acronym

MCPI = Multimodal Cocktail Periarticular Injection TKA = Total Knee Arthroplasty

IRCT registration information

IRCT registration number: **IRCT20200627047934N1**

Registration date: **2020-07-07, 1399/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-07, 1399/04/17**

Update count: **0**

Registration date

2020-07-07, 1399/04/17

Registrant information

Name

Mohammad Hossein gholy nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4204 2681

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-05, 1397/09/14

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating The Results Of Addition Of Betamethasone To Multimodal Cocktail Periarticular Injection In Bilateral Total Knee Arthroplasty

Public title

Effects of Betamethasone In Total Knee Arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People aged 50 to 90 years Having advanced osteoarthritis of both knees

Exclusion criteria:

People who did not agree to study and use their information
Contraindications to the use of the studied drugs (including known allergies or intolerance to one of the drugs, fungal infections, having heart, liver, brain, kidney disease and inflammatory diseases of the joints, people with bleeding disorders, gastrointestinal bleeding, Asthma, glaucoma, cataracts and diabetic patients)
Patients weighing more than 100 kg
Patients with neuropathic pain and sensory disturbances in the foot
Patients with a history of knee surgery

Age

From **50 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

In a group of patients, a cocktail containing betamethasone (betamethasone, Tranexamic acid, bupivacaine and ketorolac) is injected into the right knee, and a betamethasone-free cocktail (Tranexamic acid, bupivacaine and ketorolac) is injected into the left knee; In the other group, the opposite is true.

Randomization (investigator's opinion)

Randomized

Randomization description

We divide patients by randomization with 4 blocks into groups A and B. Group A includes patients who are injected with a cocktail containing betamethasone in their right knee. In group B, a cocktail containing betamethasone is injected into the left knee. On the morning of the operation, the envelope containing the patient's group will be given to the surgeon.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, researchers, physiotherapists, and all nursing staff are unaware of these groupings (A and B) (and the study is double blind). Because the surgeon is unaware of the groupings, he will have no role in postoperative care. After collecting all the data, the information will be analyzed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Islamic Azad University - Shahroud Branch

Street address

Central building, Islamic Azad University, next to the gas station, Daneshgah Blvd., Shahroud, Semnan

City

Shahroud

Province

Semnan

Postal code

3614871151

Approval date

2019-03-09, 1397/12/18

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1397.041

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

Bilateral osteoarthritis of knee

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes**1****Description**

Pain score

Timepoint

It is measured at hours 6, 18, 24, 48 and on days 7, 14 and 60 after surgery.

Method of measurement

Visual Analogue Scale

2

Description

Knee range of motion

Timepoint

It will be measured at 24, 48 hours and 7 and 60 days after surgery.

Method of measurement

Gonia meters

3

Description

Oxford Knee Score

Timepoint

It will be checked before the operation and on the 60th day after the operation

Method of measurement

questionnaire

4

Description

Wound complications

Timepoint

At any time of the visit

Method of measurement

Observation and examination

Secondary outcomes

1

Description

Patients' satisfaction with pain control

Timepoint

It will be asked at hours 24, 48 and on days 7 and 60 after the operation

Method of measurement

questionnaire

Intervention groups

1

Description

We divide patients by randomization with 4 blocks into groups A and B. Group A includes patients who are injected with a cocktail containing betamethasone in their right leg. In group B, a cocktail containing betamethasone is injected into the left leg. On the morning of the operation, the envelope containing the patient's group will be given to the surgeon. Half an hour before the operation, all patients will be injected with 1 g of intravenous Tranexamic acid, and after the operation, 500 mg of BD Tranexamic acid capsules will be given for 5 days. All patients are given 1 g of intravenous cefazolin before surgery (2 g if they weigh more than 80 kg) and 1 g of Tds after surgery. General anesthesia will be used for all patients. All joint replacement procedures will be performed using the Medial Para-Petlar Surgery Technique. Method of classification and injection of cocktails: In the knee of the intervention, 500 mg/5 ml

Tranexamic acid , 20 mg of Bupivacaine, 30 mg of Ketorolac and 6 mg of Betamethasone LA (Betamethasone acetate 3mg + Betamethasone 3 mg) are combined . The final volume of the cocktail will reach 45ml with normal saline and will be injected in two steps: The first injection is before the prostheses are placed, during which 30ml of the cocktail is applied to all the surrounding tissues except the posterolateral capsule (to prevent temporary paralysis of Proneal nerve) will be performed. The next injection contains the remaining 15 ml of the cocktail, which will be applied to the edges of the wound when it closing. Antithrombotic treatment with 40 mg subcutaneous Enoxaparin is started the day after surgery. The tourniquet is used in all patients and the drain is going out 24 hours after the operation. drawing Bandage is used compressively. Patients will walk from the night of the operation and if they do not tolerate the day after the operation. For pain control in the first 48 hours, 5mg of morphine PRN is prescribed a maximum of 3 times, 1g of Apotel ampoules TDS and one Ketorolac ampoule BD. Pain control will be performed after 48 hours with 15 mg of Meloxicam daily and 1g of Acetaminophen 3 times a day. To compare the two cocktails, we will divide the knees into two groups A (in which a cocktail containing Betamethasone is injected) and B (in which a cocktail without Betamethasone is injected).

Category

Treatment - Drugs

2

Description

Control Knee: In this group, betamethasone-free injectable cocktail (500 ml / mg 5 mg tracenamic acid, 20 mg bupivacaine, 30 mg ketorolac) is made. The final volume of the cocktail with normal saline will reach 45ml. The rest of the steps will be similar to the intervention knee.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam al Anbilya Hospital

Full name of responsible person

Farivar bagheri

Street address

Khatam al anbya Hospital, Daneshgah Bulv, shahroud city, semnan

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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?**

Yes

Title of funding source

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Farivar Bagheri

Position

Phd, Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Mohammad Hossein Gholy Nejad

Position

Intern

Latest degree

A Level or less

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General Practitioner

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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

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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