Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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
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Iran (Islamic Republic of)
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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
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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 protheses 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
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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?
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
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Farivar Bagheri
Position
Phd, Assistant Professor
Latest degree
Specialist
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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