

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Preemptive Injection of Periarticular-Multimodal Drug for Postoperative Pain Management in Total Knee Arthroplasty: A double-blind randomized clinical trial.

Protocol summary

Summary

- Main aim: To investigate the effect of a periarticular multimodal drugs injections preemptively on postoperative pain control and functions of knee following total knee arthroplasty (TKA). - Type of study: A double-blind, placebo-controlled, randomized clinical trial. - Population of study: 120 eligible individuals - aged 30 to 80 years old, were scheduled for primary unilateral Total Knee Arthroplasty. - Inclusion criteria: Individuals with osteoarthritis who were scheduled for primary unilateral TKA. - Exclusion criteria: BMI greater than 40; previous history of allergy to any medications; known abuser of alcohol and other drugs; any inflammatory arthritis; previous major surgery in the same knee joint indicated for TKA; necessity for bilateral TKA; patient's disinclination for the follow-up. - Sample size: 120 eligible patients were randomly divided to one of two groups: the intervention group (60) and the control group (60). Interventions: Intervention group: Preemptive Injection of Periarticular-Multimodal Drug including Bupivacaine hydrochloride (0.5%) 50 mg, Morphine sulfate 10 mg, Epinephrine (1:1000) 300 mcg and ketorolac 30 mg which were all diluted by 0.9 % sodium chloride solution to make a total of 100 ml. Control group: Preemptive Injection of Epinephrine (1:1000) that also was diluted in 0.9 % sodium chloride to make a total of 100 ml. Time of intervention: The injections were given 15 minutes before incision. - Outcomes: Primary outcome: Severity of pain. Secondary outcome: Function of knee joint.

General information

Acronym

TKA: Total knee arthroplasty, KSS: Knee Society Score, VAS: Visual Analog Scale.

IRCT registration information

IRCT registration number: **IRCT2016073129132N2**

Registration date: **2016-08-24, 1395/06/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-24, 1395/06/03

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-11-30, 1394/09/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preemptive Injection of Periarticular-Multimodal Drug for

Postoperative Pain Management in Total Knee Arthroplasty: A double-blind randomized clinical trial.

Public title

Preventive injection of some types of pain-relief drugs around knee joint for management of pain after complete replacement of knee joint.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: individuals with osteoarthritis who were scheduled for primary unilateral TKA. Exclusion criteria: BMI greater than 40; previous history of allergy to any medications; known abuser of alcohol and other drugs; any inflammatory arthritis; previous major surgery in the same knee joint indicated for TKA; individuals who were candidates for bilateral TKA; patients who did not show up for the follow-up.

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hezarjarib St.

City

Isfahan

Postal code

73461-81746

Approval date

2014-10-21, 1393/07/29

Ethics committee reference number

394048

Health conditions studied

1

Description of health condition studied

Arthrosis of knee (Gonarthrosis)

ICD-10 code

M17.1

ICD-10 code description

Other primary gonarthrosis

2

Description of health condition studied

Severity of pain after Total Knee Arthroplasty

ICD-10 code

T84.8

ICD-10 code description

Other complications of internal orthopaedic prosthetic devices, implants and grafts

3

Description of health condition studied

Total Knee Arthroplasty

ICD-10 code

Z96.8

ICD-10 code description

Presence of other specified functional implants

Primary outcomes

1

Description

the severity of the pain in knee joint.

Timepoint

24 hours, 48 hours and 6 weeks after the surgery

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

1

Description

function of knee joint

Timepoint

6 weeks and 6 months after surgery

Method of measurement

Knee Society Score

Intervention groups

1

Description

Intervention group: Intervention Name: Preemptive Injection of Periarticular-Multimodal Drug Intervention Description: Injection of a cocktail including Bupivacaine hydrochloride 0.5% (AstraZeneca, Cenexi, France) 50 mg, Morphine sulfate 10 mg (Darou Pakhsh, Tehran, Iran),

Epinephrin (1:1000) (Darou Pakhsh, Tehran, Iran) 300 mcg and ketorolac (Caspian Tamin, Rasht, Iran) 30 mg which are all diluted by 0.9 % sodium chloride solution to make a total of 100 ml (15 minutes before surgery).

Category

Treatment - Drugs

2**Description**

Control group: Intervention name: Routinely preemptive Injection Intervention description: Preemptive Injection of Epinephrine (1:1000) that also been diluted in 0.9 % sodium chloride to make a total of 100 ml (15 minutes before surgery).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayat-Allah Kashani Teaching Hospital

Full name of responsible person

Dr. Mehrdad Rogha

Street address

Ayat-Allah Kashani Street.

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Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences and Health Cares.

Full name of responsible person

Fariba Vakili

Street address

Hezarjarib St., Isfahan University of Medical Sciences and Health Cares, School of Medicine, Research affairs.

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Isfahan

Grant name**Grant code / Reference number**

394048

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Isfahan University of Medical Sciences and Health Cares.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Isfahan University of Medical Sciences

Full name of responsible person

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Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty