

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

The Effect of Magnesium Sulphate on Postoperative Pain and Opioid Consumption in Total knee arthroplasty

Protocol summary

Study aim

The effect of injectable magnesium sulfate on pain and reducing the need for opioids after total knee arthroplasty

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients. Random allocation software was used for randomization.

Settings and conduct

Injection of magnesium sulfate into patients undergoing total knee arthroplasty

Participants/Inclusion and exclusion criteria

All individuals with a diagnosis of knee replacement surgery; Patients with diabetes, liver dysfunction, renal dysfunction, heart disorders, high blood pressure, neurological diseases, respiratory diseases, coagulation disorders, congenital diseases, pregnant women and mothers during breastfeeding, people taking calcium channel blockers, people who have received magnesium supplement in the last month before and during the study, people with serum magnesium above 2.8, sensitive people or contraindicated in fentanyl and Apotel

Intervention groups

1- The intervention group received 4 g of magnesium sulfate (equivalent to 8 cc of 50% magnesium sulfate) in 250 cc of normal saline by infusion 30 minutes before the operation, during the operation and up to 2 hours after the operation. 2 -The control group received 8 cc and 250 cc of normal saline (as an infusion with the same volume as the intervention group) 30 minutes before the operation, during the operation and up to 2 hours after the operation.

Main outcome variables

Measurement of patient pain with visual analogue scale and numerical rating scale at times immediately after surgery, 2, 4, 6, 12 and 24 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161204031229N6**

Registration date: **2022-03-23, 1401/01/03**

Registration timing: **retrospective**

Last update: **2022-03-23, 1401/01/03**

Update count: **0**

Registration date

2022-03-23, 1401/01/03

Registrant information

Name

Azadeh Eshraghi

Name of organization / entity

Department of Clinical Pharmacy, Faculty of Pharmacy-International Campus, Iran University of Medica

Country

Iran (Islamic Republic of)

Phone

+98 86709

Email address

eshraghi.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

2021-05-22, 1400/03/01

Actual recruitment end date

2021-07-23, 1400/05/01

Trial completion date

Scientific title

The Effect of Magnesium Sulphate on Postoperative Pain and Opioid Consumption in Total knee arthroplasty

Public title

The effect of magnesium sulfate in reducing the pain of knee replacement surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All volunteers for Total knee arthroplasty

Exclusion criteria:

Diabetes Renal Disorder Hepatic Disorder Consumption of Calcium Blocker agents Consumption of Magnesium supplements before the study Consumption of Magnesium supplements during the study in the last month magnesium level more than 2.8 Pregnancy Lactation

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (quadruple blocks) All possible blocks are arranged as follows: block 1: ABAB block 2: AABB block 3: ABBA block 4: BBAA block 5: BABA block 6: BAAB We need 15 blocks to select 60 people. We randomly select these blocks from the numbers 1 to 6. Using R software, we choose a random number between the numbers 1 to 6. For example, number 6 is chosen as the first block and number 2 as the forth block. The people who enter the study are given B-A-A-BA- A-B-B, respectively. Finally, group A receives control intervention and group B receives treatment intervention

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher is unaware that the medicine given to the patient is the main medicine or placebo. The participant (patient) is also unaware that the medicine being given to them is the main medicine or placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2021-01-04, 1399/10/15

Ethics committee reference number

IR.IUMS.REC.1399.1067

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

Total knee arthroplasty

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

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

Evaluate the patient's pain

Timepoint

Immediately after surgery, 2, 4, 6, 12 and 24 hours after surgery

Method of measurement

Use visual analogue scale and numerical rating scale

2**Description**

Serum level of magnesium sulfate

Timepoint

Daily

Method of measurement

Laboratory methods

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 4 g of magnesium sulfate (equivalent to 8 cc of 50% magnesium sulfate) in 250 cc of normal saline was infused 30 minutes before the operation, during the operation and up to 2 hours after the operation.

Category

Rehabilitation

2

Description

Control group: 8 cc and 250 cc normal saline (by infusion with the same volume as the magnesium group) were given 30 minutes before the operation, during the operation and up to 2 hours after the operation.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul akram hospital

Full name of responsible person

Mehdi Moghtadaei

Street address

Tehran, Sattar khan St.

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mmoghtadaei@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motevalian

Street address

Shahid Hemmat Gharb Highway - Between the Intersection of Sheikh Fazlullah Nouri and Shahid Chamran

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Azadeh Eshraghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Tehran - Sattar Khan - st. Prayer - Corner of Mansouri Street - Hazrat Rasool Akram Hospital

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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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

The main consequence

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Total data

From where data/document is obtainable

Email: aepharm@gmail.com

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

by Email

Comments