

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study of the effectiveness of adding magnesium sulfate to Ropivacaine comparing to the addition of Tramadol to Ropivacaine on the beginning of analgesia and the level of block and analgesia in patients undergoing lower limb orthopedic surgery

Protocol summary

Study aim

Study of the effectiveness of adding magnesium sulfate to Ropivacaine comparing to the addition of Tramadol to Ropivacaine on the beginning of analgesia and the level of block and analgesia in patients undergoing lower limb orthopedic surgery

Design

This study is a double-blinded clinical trial. The study population will be included all patients undergoing lower limb surgery who will refer to Taleghani Hospital of Kermanshah city. 110 eligible patients will be selected conveniently and randomly will be assigned to two intervention groups.

Settings and conduct

This study that will be conducted in Taleghani hospital of Kermanshah city is double-blinded one. In this way that patients and researchers will be blinded to the study groups, the dosage of the drug and the manufacturer of the medicine. At the beginning of the study, the diastolic and systolic blood pressure, and the number of pulses of both groups are recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 16 -60 years; Anesthesia level 1 to 10 Exclusion criteria: Patients with underlying illness include high blood pressure, pulmonary disease, cardiovascular disease; Drug users patients

Intervention groups

The first intervention group in addition to Ropivacaine ,will receive 100 mg magnesium sulfate 15 minutes before the surgery. The second intervention group, in addition to Ropivacaine will receive 10 mg tramadol 15 minutes before the surgery

Main outcome variables

Pain; nausea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N116**

Registration date: **2019-03-10, 1397/12/19**

Registration timing: **prospective**

Last update: **2019-03-10, 1397/12/19**

Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-16, 1397/12/25

Expected recruitment end date

2019-06-15, 1398/03/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of adding magnesium sulfate to Ropivacaine comparing to the addition of Tramadol to Ropivacaine on the beginning of analgesia and the level of block and analgesia in patients undergoing lower limb orthopedic surgery

Public title

Study of the effectiveness of adding magnesium sulfate to Ropivacaine comparing to the addition of Tramadol to Ropivacaine on the beginning of analgesia in patients undergoing lower limb orthopedic surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 16 -60 years Anesthesia level 1 to 10

Exclusion criteria:

Patients with underlying illness include high blood pressure, pulmonary disease, cardiovascular disease
Drug users patients

Age

From **16 months** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **115**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and researcher will be blinded to the study groups, the dosage of the drug and the manufacturer of the drug

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-12-26, 1397/10/05

Ethics committee reference number

ir.kums.rec.1397.790

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

Postoperative pain of lower limb orthopaedic surgery

ICD-10 code

M79.6

ICD-10 code description

Pain in limb, hand, foot, fingers and toes

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

Pain

Timepoint

The beginning and end of the study

Method of measurement

Based on the visual scale of pain

2**Description**

Nausea

Timepoint

The beginning and end of the study

Method of measurement

Asking the patient

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group in addition to Rupivacaine ,will receive 100 mg magnesium sulfate ,15 minutes before the surgery

Category

Treatment - Drugs

2

Description

The second intervention group, in addition to Rupivacaine will receive 10 mg tramadol 15 minutes before the surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

Behnam Yari Bajlani

Street address

Taleghani Hospital, Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 7985

Email

dr_m20081362@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Behnam Yari Bajlani

Position

M.A student of special care

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Email

dr_m20081362@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Maryam Rahmatinejad

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Taleghani Hospital, Shahid Beheshti Blvd

City

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Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Behnam Yari Bajlani

Position

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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

Not applicable

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments