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 bebe 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 Rupivacaine ,will receive 100 mg magnesium sulfate 15 minutes before the surgery. The second intervention group, in addition to Rupivacaine 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
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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
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6715847141
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+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
Street address
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Full name of responsible person
Dr. Maryam Rahmatinejad
Position
Anesthesiologist
Latest degree
Specialist
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Email

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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

M.A student of special care

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Taleghani Hospital, Shahid Beheshti Blvd

City

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Postal code

6715847141

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Email

dr_m20081362@yahoo.com

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