

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the effect of combined of (bupivacaine + magnesium sulfate) with combined (pethidine + magnesium sulfate) and sole pethidine in spinal anesthesia on effect of duration and hemodynamic changes in patients under Lower Limb orthopedic surgery

Protocol summary

Study aim

Determining the effect of combination (bupivacaine + magnesium sulfate) with the combination (pethidine + magnesium sulfate) and alone on the duration of action and hemodynamic changes in patients undergoing orthopedic surgery with lower limb fractures

Design

Clinical trial with control group, block randomization, thirty patients in each group with parallel groups, double blinded

Settings and conduct

This study will be conducted at Golestan University of Medical Sciences in the operating room of Gorgan 5th Azar Hospital in 2020. Patients in 4 control groups will receive medication interventions. After the injection, the sensation block time will be recorded using a blunt needle and the motion block will be recorded using the bromage scale and the duration of the sensory and motor block and possible hemodynamic changes in patients. In order to perform the method of blinding the patient, the statistical evaluator and analyst will not be aware of the type of groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patient with lower limb fracture candidate for orthopedic surgery which can be performed under spinal anesthesia 2- Signing a consent form 3- Class 1 or 2 ASA physical condition 4- Age 18-60 years old 5- Elective surgery Exclusion criteria: 1- High intracranial pressure 2. Infection in injection site 3- Impossible of proper position

Intervention groups

Group A : 100 mg of magnesium sulfate with bupivacaine at a dose of 10 mg). Group B :100 mg of magnesium sulfate with pethidine at a dose of 1 mg / kg group C: Pethidine 1 mg / kg alone group D: bupivacaine with a dose of 10 mg alone

Main outcome variables

duration of anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170413033408N3**

Registration date: **2020-06-11, 1399/03/22**

Registration timing: **prospective**

Last update: **2020-06-11, 1399/03/22**

Update count: **0**

Registration date

2020-06-11, 1399/03/22

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 9891

Email address

dr.mojaveraghili@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-20, 1399/05/30

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of combined of (bupivacaine + magnesium sulfate) with combined (pethidine + magnesium sulfate) and sole pethidine in spinal anesthesia on effect of duration and hemodynamic changes in patients under Lower Limb orthopedic surgery

Public title

Comparison of the effect of drug combination in lower back anesthesia on duration of effect and changes in heart rate and blood pressure in patients undergoing orthopedic surgery with lower limb fractures

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with lower limb fracture candidate for orthopedic surgery which can be performed under spinal anesthesia
Signing a consent form
Class 1 or 2 of the physical condition of the American Anesthesia Association ASA
Age range 18-60 years
Elective surgery

Exclusion criteria:

High intracranial pressure
Infection in site of injection
Impossible of proper position
History of allergy with bupivacaine or pethidine

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the participants who have the conditions to enter the study, using the random blocks method, these people will be assigned to four groups A, B, C, D. According to the sample size of 30 in the groups, all four blocks of letters A, B, C and D are considered and thirty blocks will be randomly selected; In a random process, a sequence of one hundred and twenty letters A, B, C, D will be created, then this sequence will be numbered from one to 120 numbers. Numbers one to 120 will be placed in a bag, and the researcher will randomly select one of the numbers for each eligible person in the present study, based on the selected number in one of the letters A, B, C, D (respectively to Combination groups (Bupivacaine + Magnesium Sulfate), Combination (Pethidine + Magnesium Sulfate), Pethidine and

Bupivacaine will be done.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, in order to perform the method of blinding the patient, the statistical evaluator and analyst will not be aware of the type of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Golestan University of Medical Sciences Ethics Committee

Street address

Gorgan-sari road 4th kilometer, Golestan University of Medical Science

City

Gorgan

Province

Golestan

Postal code

4917763681

Approval date

2020-03-18, 1398/12/28

Ethics committee reference number

IR.GOUMS.REC.1398.400

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

Lower Limb fracture

ICD-10 code

M89.9

ICD-10 code description

Disorder of bone, unspecified

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

The duration of the anesthetic effect

Timepoint

The duration of anesthesia will be recorded every minute immediately after intravenous injection until the onset of sensory block and every 5 minutes until sensory level stabilization.

Method of measurement

Using a blunt needle and register in the checklist

2

Description

Hemodynamic change

Timepoint

Hemodynamic changes in the operating room will be measured every 5 minutes until the end of the first 30 minutes, then every 15 minutes until the end of surgery. The recovery room will record every 15 minutes until recovery criteria are met..

Method of measurement

Hemodynamic criteria (heart rate, systolic, diastolic, and mean arterial blood pressure (MABP), arterial oxygen saturation) of the patient will be measured by Saadat monitoring.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A patients will receive Intrathecal magnesium sulfate with 100 mg bupivacaine at a dose of 10 mg.

Category

Treatment - Drugs

2

Description

Intervention group: Group B will be patients receiving 100 mg of Intrathecal magnesium sulfate with pethidine at a dose of 1 mg / kg .

Category

Treatment - Drugs

3

Description

Intervention group: group C Petdin 1 mg / kg will be injected into the spinal cord

Category

Treatment - Drugs

4

Description

Control group: Group D Bupivacaine will be injected Intrathecal at a dose of 10 mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gorgan 5 Azar Educational and Medical Center

Full name of responsible person

Dr.Babak mojaver aghili

Street address

Gorgan-Sari road 4th kilometers, Golestan University of Medical Sciences, School of Medicine - Anesthesiology Department

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Honarvar

Street address

Golestan University of Medical Sciences, Deputy of research and technology-Gorgan-Gorgan-Sari 4th kilometer,

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

dr Babak Mojaver Aghilli

Position

Anesthesiologist, Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Contact

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Seyed babak Mojaveraghili

Position

Assistant Professor - Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

Anesthesiology

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information on the main outcome

When the data will become available and for how long

Since 2021

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

No manipulation, mentioning the data reference

From where data/document is obtainable

Seyed Babak Mojaver Aghili, drbabaka35@gmail.com, Golestan University of Medical Sciences, Deputy of Research and Technology, Gorgan, Golestan, Iran, Gorgan, 4 km, Sari,

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

sending an email, complete the personal and professional characteristics with documentation

Comments