Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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. I 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- Ellecitve 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 (Pethdine + Magnesium Sulfate), Pethdine 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
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Full name of responsible person
Dr Mohammadreza Honarvar
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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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Person responsible for updating data

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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