

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effect of interathecal injection of pethidine versus bupivacaine on hemodynamics in hip surgery.

Protocol summary

Study aim

Determination the Effect of interathecal Petidine Injections in Comparison with intrathecal Bupivacaine on Hemodynamic Stability in Hip Surgery.

Design

A triple blinded randomized clinical trial with parallel groups. 60 patients participated in the study and they were divided into two groups (30 patients in each group).

Settings and conduct

This study will be carried out in the operating room of 5th Azar hospital in Gorgan city. Anesthesia and recording of vital signs will be done by the resident of anesthesiology who is unaware of the drug type being injected

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with hip or femoral fractures.
Exclusion criteria: Allergy to Local Anesthetics and Pethidine; Coagulation Disorders; Patients refusal inability to maintain position during needle puncture; localized sepsis of the puncture site; High Intra Cranial Pressure.

Intervention groups

All patients admitted to the hospital with a hip and femoral fracture and are candidates for surgery, are going to be examined to enter the study. Patients are going to be categorized into two intervention groups. In intervention group1 patients are going to be anesthetized by intrathecal injection of 1 mg/kg Pethidine(Aburaihan pharmaceutical Co.), which is diluted by normal saline until it reaches 2 mL volume. In intervention group 2 patients are going to be anesthetized by intrathecal injection of 2 mL room temperatured Bupivacaine 0.5%(equall to 10 mg of bupivacaine) produced by Mylan Co.

Main outcome variables

Heart rate per minute, mean arterial pressure, systolic blood pressure, diastolic blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180603039966N1**

Registration date: **2018-08-31, 1397/06/09**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-31, 1397/06/09**

Update count: **0**

Registration date

2018-08-31, 1397/06/09

Registrant information

Name

Sina Hasannasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3235 2508

Email address

sina.hasannasab@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of interathecal injection of pethidine versus bupivacaine on hemodynamics in hip surgery.

Public title

Comparison the effect of interathecal injection of pethidine versus bupivacaine on hemodynamics

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with hip or femoral fractures

Exclusion criteria:

Allergy to Local Anesthetics and Pethidine Coagulation Disorders Patients refusal inability to maintain position during needle puncture localized sepsis of the puncture site High Intra Cranial Pressure

Age

From 20 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is going to be performed using sequentially numbered, sealed, non-opaque envelopes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Considering the design of the research and the method of randomization and implementation of latent structure, just the supervisor is aware of the syringe contents which is labeled with A or B. In this research, not only the patients, but also the observer (Resident of anesthesiology who perform the block and record the vital signs) and the statistical analyst are also unaware of the syringe contents and which letter (A or B) belong to which intervention groups. So this research is a triple blinded which is performed via sequentially numbered, sealed, non-opaque envelopes.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Golestan University of Medical Sciences

Street address

Shast Kola road, Hirkan Blvd

City

Gorgan

Province

Golestan

Postal code

4934174515

Approval date

2018-05-20, 1397/02/30

Ethics committee reference number

IR.GOUMS.REC.1397.017

Health conditions studied

1

Description of health condition studied

Fractures of the hip and femor

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Heart Rate per minute

Timepoint

Heart rate per minute, will be recorded on minutes 0, 3, 6, 9, 12, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 75, 90 and every 30 minute after that.

Method of measurement

vital signs will be measured by Saadat (Alborz B9) patient's monitoring device

2

Description

Mean Arterial Pressure (MAP)

Timepoint

Mean Arterial Pressure (MAP), will be recorded on minutes 0, 3, 6, 9, 12, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 75, 90 and every 30 minute after that.

Method of measurement

vital signs will be measured by Saadat (Alborz B9) patient's monitoring device

3

Description

Systolic Blood Pressure

Timepoint

Systolic Blood Pressure, will be recorded on minutes 0, 3,

6, 9, 12, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 75, 90 and every 30 minute after that.

Method of measurement

vital signs will be measured by Saadat (Alborz B9) patient's monitoring device

4

Description

Diastolic Blood Pressure

Timepoint

Diastolic Blood Pressure, will be recorded on minutes 0, 3, 6, 9, 12, 15, 20, 25, 30, 35, 40, 45, 50, 55, 60, 75, 90 and every 30 minute after that.

Method of measurement

vital signs will be measured by Saadat(Alborz B9) patient's monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: patients with hip or femor fractures, who are candidates for surgery, are going to be anesthetized by intrathecal injection of 1 mg/kg Pethidine(Aburaihan pharmaceutical Co.), which is diluted by normal saline until it reaches 2 mL volume.

Category

Treatment - Drugs

2

Description

Intervention group 2: patients with hip or femor fractures, who are candidates for surgery, are going to be anesthetized by intrathecal injection of 2 mL room temperatured Bupivacaine 0.5%(equall to 10 mg of bupivacaine) produced by Mylan Co.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar hospital

Full name of responsible person

Babak Mojaver Aghili

Street address

5 Azar street

City

Gorgan

Province

Golestan

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4917763681

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+98 17 3222 0561

Email

Dr.mojaveraghili@goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

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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

Babak Mojaver Aghili

Position

assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Assistant Proffessor
Latest degree
Specialist
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person

Sina Hasannasab
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resident
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Medical doctor
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sina.hasannasab@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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