

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 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

Postal code

4917763681

Phone

+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

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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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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