Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effect of interautal administration of bupivacaine and dextrose 5% and fentanyl on bupivacaine alone on the onset and duration of analgesia in patients undergoing lower limb orthopedic surgery

Protocol summary

Study aim

Comparison of the effect of interautal administration of bupivacaine and dextrose 5% and fentanyl on bupivacaine alone on the onset and duration of analgesia in patients undergoing lower limb orthopedic surgery

Design

Clinical trial with control group, with parallel group; Double blind, randomized

Settings and conduct

This study is being performed at Imam Reza Hospital in Birjand, South Khorasan Province. 40 patients are randomly divided into two intervention groups, one and two. After anesthesia in patients and interventions related to each group, the amount of pain in each group at 0, 6, 12 and 24 hours after surgery, patients' blood pressure, heart rate and duration of pain by the nurse in the evaluation department will be.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: having informed consent, patients with ASA class one and two, age between 20 and 50 years, no drug addiction, no spinal history following surgery in the past week, no pregnancy, no brain trauma. The most recent is spinal deformity. Exclusion criteria include: patients' dissatisfaction to continue studying, duration of surgery more than 1 hour, inability to position the patient, spinal infection, sensitivity to local anesthetic drugs, high ICP and coagulation disorders.

Intervention groups

The first group under spinal by prescribing marcain 0.5% to 2 cc (10 mg) and the second group under spinal by prescribing marcain 0.5% 1 cc (5 mg) + 25 micrograms fentanyl (cc 0.5) + 0.5 cc of 5% sterile dextrose.

Main outcome variables

the pain Painless duration blood pressure heart beat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N2**
Registration date: **2020-04-30, 1399/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-30, 1399/02/11**
Update count: **0**

Registration date

2020-04-30, 1399/02/11

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of interautal administration of bupivacaine and dextrose 5% and fentanyl on bupivacaine alone on the onset and duration of analgesia in patients undergoing lower limb orthopedic surgery

Public title
Comparison of onset and duration of pain prescribed by combination of bupivacaine with 5% dextrose and fentanyl with bupivacaine

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having conscious patient satisfaction Patients with ASA class one and two Age between 20 and 50 years No drug addiction No spinal history following surgery in the past week No pregnancy Nhere is no spinal deformity There is no spinal deformity

Exclusion criteria:
Patient dissatisfaction to continue studying Duration of surgery over 1 hour Inability to position the patient Spinal Infection Sensitivity to local Anesthetic Drugs High ICP Coagulation Disorders

Age
From **20 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **20**

Randomization (investigator's opinion)
Randomized

Randomization description
Individuals in each group will be randomly randomized and blocked, including spinal patients with a marcain prescription of 0.5% to cc 2 (10 mg) of group A, and the second group of spinal cord group B with a spinal margin prescription of 5 marcain. %0.5 cc 1 (mg 5) + micg 25 fentanyl (cc 0.5) + cc 0.5 dextrose will be 5% sterile. First, a variety of four blocks are created (AABB, BBAA, ABAB, BABA, ABBA, and BABA). Randomly one of these blocks is selected and patients will be divided into A or B by one of two surgical groups. Then the same is done for other patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
Study participants without knowledge of the drug received for pain relief. Outcome Assessor: The ward nurse questions patients from patients without knowing the type of medication they are taking and registers them in the relevant checklist.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences

Street address
Ghafaree St

City
Birjan

Province
South Khorasan

Postal code
9717811674

Approval date
2020-02-10, 1398/11/21

Ethics committee reference number
IR.BUMS.REC.1398.351

Health conditions studied

1

Description of health condition studied
Fracture of shaft of tibia

ICD-10 code
S82.2

ICD-10 code description
Fracture of shaft of tibia

Primary outcomes

1

Description
Pain

Timepoint
0, 6, 12and 24 hours after surgery

Method of measurement
Using of VAS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This group under spinal by prescribing marcain 0.5% 1 cc (5 mg) + 25 micrograms fentanyl (cc 0.5) + 0.5 cc of 5% sterile dextrose.

Category

Treatment - Drugs

2

Description
Control group: this group under spinal by prescribing marcain 0.5% to 2 cc (10 mg)
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam reza hospital
Full name of responsible person
Aram Meshkini
Street address
Moallem St
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9717811674
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Dr. Tooba kazemi
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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
Birjand 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
Birjand University of Medical Sciences
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Zabihullah Mohaghegh
Position
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Person responsible for updating data

Contact

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Position
student

Latest degree
Bachelor

Other areas of specialty/work
General Practitioner

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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 need to publish individual patient 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