Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effect of addition of 5 mg meperidine to 10 mg bupivacaine for spinal anesthesia on postoperative pain in cesarean section surgery.

Protocol summary

Summary

The aim of this study was to evaluate the effect of meperidine 5 mg as an additive to bupivacaine for spinal anesthesia on postoperative pain in cesarean section surgery. This double blind randomized clinical trial study was performed on 40 patients aged 20-50 yr with American society anesthesia physical classification system (ASA) 1 or 2 were scheduled for elective cesarean surgery under spinal anesthesia. Patients were randomized according to usage of meperidine or normal salin as an additive to bupivacaine for spinal anesthesia. All patients with pre-existing or pregnancy-induced hypertension, known fetal abnormality or allergy to bupivacaine or meperidine were excluded. Postoperative analgesia was compared between two groups immediately and 2, 12, 24 hours after surgery. Also, the need for antiemetic was compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015052821383N2**
Registration date: **2016-03-20, 1395/01/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-03-20, 1395/01/01

Registrant information

Name

Amir Saber Tanha

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences.

Expected recruitment start date

2015-02-05, 1393/11/16

Expected recruitment end date

2015-08-07, 1394/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of addition of 5 mg meperidine to 10 mg bupivacaine for spinal anesthesia on postoperative pain in cesarean section surgery.

Public title

The effect of addition of meperidine to intrathecal bupivacaine on postoperative pain after cesarean section.

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: all patients 20-50 years with score 1-2 according to American Society of Anesthesia classification for risk of anesthesia were scheduled for cesarean section under spinal anesthesia. Exclusion criteria: pre-existing or pregnancy-induced hypertension, known fetal abnormality or allergy to bupivacain or

mepridine.

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Birjand University of Medical Sciences

Street address
Birjand University of Medical Sciences, Ghafari Street, Birjand

City
Birjand

Postal code

Approval date
2015-01-26, 1393/11/06

Ethics committee reference number
1393-11-01

Health conditions studied

1

Description of health condition studied
Cesarean section

ICD-10 code
O30-048

ICD-10 code description
Maternal care related to the fetus and amniotic cavity and possible delivery problems

Primary outcomes

1

Description
Postoperative pain

Timepoint
Immediately after surgery, 2, 12, 24 hours after surgery

Method of measurement
Visual analog score of pain

Secondary outcomes

1

Description
Intraoperative nausea and vomiting

Timepoint
Intraoperative

Method of measurement
Incidence of vomiting or need for administration of antiemetic drug.

Intervention groups

1

Description
Intrathecal injection of 0.5% hyperbaric bupivacaine 2.0 ml plus normal saline 0.5 ml

Category
Prevention

2

Description
Intrathecal injection of 0.5% hyperbaric bupivacaine 2.0 ml plus 1% meperidine 0.5 ml

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr hospital of Birjand University of Medical Sciences

Full name of responsible person
Dr. Amir Saber Tanha

Street address
Valiasr hospital, Ghafari Street, Birjand

City
Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person

Dr. Asghar Zarban

Street address

Birjand University of Medical Sciences, Ghafari Street, Birjand

City

Birjand

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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Position

Assistant professopr of anesthesia

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty