Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study of low dose intrathecal meperidine on intra- and post-operative shivering in caesarean section under spinal anesthesia:a prospective double-blind, randomized Clinical Trial

Protocol summary

Summary

The aim of this double-blind, randomized clinical trial study is to demonstrate the incidence and intensity of intra- and post-operative shivering on Seventy parturients;American Society of Anesthesiologists (ASA) physical status I to II; aged 18 to 40 years who will refer to Jahrom University of Medical Sciences educational hospitals for elective cesarean section under spinal anesthesia. We will exclude those Parturients who had contraindication to the local anesthesia and caesarean section surgery, diabetes, preoperative body temperature>38 C(fever), sever preeclampsia, allergy to the study medications (meperidine and bupivacaine); ASA III and higher.We will enroll 70 parturients into the study and will divide them into two groups, randomly. The parturients in case group will receive 10 mg bupivacaine 0.5% plus 10 mg meperidine and those in control group will receive 10 mg bupivacaine 0.5% plus 10 mg normal saline as a placebo. Finally, all data will be collected by a blinded observer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012090410743N1**
Registration date: **2012-11-30, 1391/09/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-11-30, 1391/09/10

Registrant information

Name

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Name of organization / entity

Shiraz University of medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research -Jahrom University of Medical Sciences

Expected recruitment start date

2012-10-06, 1391/07/15

Expected recruitment end date

2012-10-16, 1391/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of low dose intrathecal meperidine on intra- and post-operative shivering in caesarean section under spinal anesthesia:a prospective double-blind, randomized Clinical Trial

Public title

Meperidine effect on intraoperative and postoperative shivering of caesarean section under spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: parturients [ASA physical status I or II]; age between 18 - 40 years old. exclusion criteria: sever

preeclampsia; contraindication to local anesthesia and caesarean section surgery; diabetes; preoperative body temperature>38oC (fever); allergy to the study medications (meperidine and bupivacaine); ASA III; drug addiction; height <152 cm; Raynaud’s syndrome; hypo or hyperthyroidism; BMI less than 19; BMI high than 25;

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

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
Jahrom University of Medical Sciences ethics Committee

Street address
Ostad Motahhari Street, site of Paradise

City
jahrom

Postal code
987414846199

Approval date
2012-08-04, 1391/05/14

Ethics committee reference number
3812/A/D

Health conditions studied

1

Description of health condition studied
Spinal anesthesia

ICD-10 code
O29.5

ICD-10 code description
Other complications of spinal and epidural anaesthesia during pregnancy

Primary outcomes

1

Description
Shivering incidence

Timepoint
Spinal Anesthesia to recovery room

Method of measurement
Crossley and Mahajan Scale

2

Description
Shivering Intensity

Timepoint
Spinal Anesthesia to recovery room

Method of measurement
Crossley and Mahajan Scale

3

Description
Systolic Blood Pressure

Timepoint
Start to end Of Surgery

Method of measurement
mmHg

4

Description
Central Core Tempreture

Timepoint
Start to end Of Surgery

Method of measurement
Celcious

5

Description
BMI

Timepoint
Start of Study

Method of measurement
KG/M2

6

Description
APGAR Score

Timepoint
Post birth

Method of measurement
APGAR Scale

7

Description
highest block Segment

Timepoint

each 5 minutes during first 30 minutes of post Spinal anesthesia

Method of measurement

Pinprick

8

Description

Diastolic Blood pressure

Timepoint

Start to end Of Surgery

Method of measurement

mmHg

9

Description

Basic heart rate

Timepoint

Start to end Of Surgery

Method of measurement

beats per min

10

Description

Basic peripheral oxygen saturation

Timepoint

Start to end Of Surgery

Method of measurement

Percent

11

Description

Surgery Duration

Timepoint

Start to end Of Surgery

Method of measurement

Minute

12

Description

Time to reach highest block

Timepoint

Anesthesia onset

Method of measurement

minute

13

Description

Sensory Level

Timepoint

Anesthesia onset

Method of measurement

Range

Secondary outcomes

1

Description

Nausea And Vomitting

Timepoint

Post operation

Method of measurement

Observation

2

Description

pruritus

Timepoint

Post operation

Method of measurement

Patient feel

3

Description

Respiratory distress

Timepoint

During and Post operation

Method of measurement

Observation

4

Description

Hypotension

Timepoint

During and Post operation

Method of measurement

mmHg

5

Description

Bradycardia

Timepoint

During and Post operation

Method of measurement

Beat per minute

6

Description

Tachycardia

Timepoint

During and Post operation

Method of measurement

Beat per minute

Intervention groups

1

Description

10 mg bupivacaine 0.5% and 10 mg meperidine by Spinal Anesthesia (group BP, n=35)

Category

Prevention

2

Description
placebo (10 mg bupivacaine 0.5% and normal saline, (group B, n=35) by spinal Anesthesia.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Motahhari Hospital, Jahrom University of Medical Sciences
Full name of responsible person
Dr. Hasan Zabetian
Street address
Anesthesia Department, Motahari hospital, Jahrom University of Medical Sciences, Motahari Avenue, Jahrom, Iran
City
Jahrom

2

Recruitment center
Name of recruitment center
Peymanieh Hospital of Jahrom University of Medical Sciences
Full name of responsible person
Dr. Hasan Zabetian
Street address
Anesthesia Department, Peymanieh Hospital of Jahrom University of Medical Sciences, Vali-asr Avenue, Jahrom, Iran
City
Jahrom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research -Jahrom University of Medical Science
Full name of responsible person
Morteza Pourahmad
Street address
Jahrom University of Medical Sciences
City
Jahrom
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for research -Jahrom University of Medical Science
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
Jahrom University of Medical Sciences
Full name of responsible person
Hasan Zabetian
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Person responsible for updating data

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Fax
Email
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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