

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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), severe 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

Mohammad Yasin Karami

Name of organization / entity

Shiraz University of medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 79 1334 0405

Email address

yasin_karami@jums.ac.ir

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: severe

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

029.5

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 Temperature

Timepoint

Start to end Of Surgery

Method of measurement

Celcius

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, Motahhari hospital, Jahrom University of Medical Sciences, Motahhari 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

Position

Associated Professor of Anesthesiology Department

Other areas of specialty/work

Street address

Jahrom University of Medical Sciences

City

Jahrom

Postal code

Phone

+98 79 1334 0405

Fax

Email

h_zabetian@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Jahrom university of Medical Sciences

Full name of responsible person

Mohammad Yasin Karami

Position

General Practitioner

Other areas of specialty/work

Street address

Motahhari Ave, Student Research Committee, Faculty of Medicine, Jahrom University of Medical Sciences, Jahrom, I.R.Iran

City

Jahrom

Postal code

Phone

+98 79 1334 0405

Fax

Email

yasinkarami@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Mohammad Amin Ghobadifar

Position

Medical Student

Other areas of specialty/work**Street address**

Jahrom University of Medical Sciences

City

Jahrom

Postal code**Phone**

00

Fax**Email****Web page address****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