

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison anti shivering effects between two different doses of intrathecal meperidine versus placebo in cesarean section

Protocol summary

Summary

Objective: Compare the effect of two different doses of meperidine intrathecal with placebo in patients who are in hospital in Sanandaj in 2015 by Caesarean section
Study design : Randomized , double-blind , placebo-controlled , single-center
Inclusion criteria: Elective cesarean section. Fill the informed consent form
Physical condition corresponding to the class I and II anesthesia
Exclusion criteria: Emergency cesarean Pregnancy associated diseases such as hypertension, diabetes
Valvular heart disease Ischemic heart disease Pulmonary hypertension Pre- eclampsia Diabetes
Sample : 150 (B) intervention or interventions studied patients divided into three groups: the first group 2/5 mL bupivacaine 0.5% and 0/5 mm saline , the second group received 2/5 ml of bupivacaine 0/5% and 0/5ml meperidine (5 mg) and 2/5 mL of bupivacaine 0.5% and the third group Meperidine 0.5 ml (10 mg) was injected (C) intervention : spinal anesthesia (D)primary outcome: post anesthesia shivering, Core temperature

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090223869N1**

Registration date: **2015-10-20, 1394/07/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-20, 1394/07/28

Registrant information

Name

Mokhtar Pouladi

Name of organization / entity

Medical University of Kurdistan

Country

Iran (Islamic Republic of)

Phone

+98 87 3182 7202

Email address

mokhtar.pouladi@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Kurdistan University of Medical Sciences

Expected recruitment start date

2015-09-16, 1394/06/25

Expected recruitment end date

2015-10-17, 1394/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison anti shivering effects between two different doses of intrathecal meperidine versus placebo in cesarean section

Public title

Effect of Meperidin on post cesarian section shivering

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Elective cesarean section ; Fill the informed consent form ; Physical condition corresponding to the class I and II anesthesia
Exclusion criteria: Emergency cesarean; Pregnancy associated diseases such as hypertension, diabetes ; Valvular heart disease ; Ischemic heart disease ; Pulmonary hypertension; Pre-eclampsia

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **150****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**

Medical University of Kurdistan-Management Student Research

Street address

Pasdaran street

City

Sanandaj

Postal code**Approval date**

2015-08-03, 1394/05/12

Ethics committee reference number

muk.rec.1394.144

Health conditions studied**1****Description of health condition studied**

caesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes**1****Description**

post anesthesia shivering

Timepoint

After intervention

Method of measurement

visual scale shivering

2**Description**

Core temperature

Timepoint

before and After intervention

Method of measurement

using omernon termoscan

Secondary outcomes**1****Description**

HR

Timepoint

Before injection and every 15 minutes during surgery

Method of measurement

using of HR recorded on monitoring

2**Description**

peak anesthesia time

Timepoint

Before injection and every 15 minutes during surgery

Method of measurement

two ways alcohol cotton and pinprek

3**Description**

Blood Pressure

Timepoint

Before injection and every 15 minutes during surgery

Method of measurement

using of BP recorded on monitoring

Intervention groups**1****Description**

The first group injected 2/5 mL bupivacaine 0.5% and 0/5 ml salin

Category

Prevention

2**Description**

The second group received 2/5 ml of bupivacaine 0/5% and 0/5ml mepridine (5 mg)

Category

Treatment - Drugs

3

Description

The third group received 2/5 mL of bupivacaine 0.5% and Mepridine 0.5 ml (10 mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Women Operation Room of Sanandaj Besat Hospital

Full name of responsible person

Mokhtar Pouladi-Medical Student

Street address

Wakil four-way

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kurdistan University of Medical Sciences

Full name of responsible person

Karim Naseri-Anesthesiologist

Street address

Pasdaran Street

City

Sanandaj

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 of Kurdistan 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

Kurdistan University of Medical Science

Full name of responsible person

Mokhtar Pouladi

Position

Intern

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Kurdistan University of Medical Science

Full name of responsible person

Karim Naseri

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Person responsible for updating data

Contact

Name of organization / entity

Kurdistan University of Medical Science

Full name of responsible person

Mokhtar Pouladi

Position

Intern

Other areas of specialty/work

Street address

Razi Residence

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Sanandaj

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Phone

+44 43230592

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