Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 mepiridine 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 salin , the second group received 2/5 ml of bupivacaine 0/5% and 0/5ml mepridine (5 mg) and 2/5 mL of bupivacaine 0.5% and the third group Mepridine 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

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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 Mepridin 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 recived 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
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Intern
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Person responsible for updating data

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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