

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of intravenous meperidine vs intratechal meperidine on shivering during delivery under spinal anaesthesia

Protocol summary

Summary

After getting the approval of the local committee of ethics in Bushehr university of medical sciences 78 patients ASA 1 and 2 age between 15 and 45 who are candidates for caesarean section and signed informed consent were randomly allocated into two groups. Control group receive 12.5 mg bupivacaine plus 12.5 mg meperdie up to 3 cc Intratechaly, Intervention group receive 12.5 mg bupivacaine plus .5 milliliter of normal saline up to 3 cc Intratechaly. In this group 12.5mg meperdie will be injected intravenously before operation. Shivering, hemodynamic change, nausea and vomiting and pain will be recorded and compared among the study groups. The level of anesthesia in all two groups is T4. The site of needle insertion is T4-T5 by gauge number 24. The monitoring in the two group were the same (NIBPM, Pulse oximetry, HR in minute 1, 3, 10, 20, 30, 45 and in recovery room. Shivering were classified as CROOSLY described. The primary end point is incidence of shivering in groups. The secondary endpoint is incidence of nausea and vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301261936N11**

Registration date: **2013-02-06, 1391/11/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-06, 1391/11/18

Registrant information

Name

Abdolreza Najafi Anaraki

Name of organization / entity

Bushehr University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 77 1354 0088

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Recruitment status

Recruitment complete

Funding source

Bushehr University of Medical Sciences

Expected recruitment start date

2013-02-05, 1391/11/17

Expected recruitment end date

2013-03-05, 1391/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intravenous meperidine vs intratechal meperidine on shivering during delivery under spinal anaesthesia

Public title

The effect of intravenous meperidine vs intratechal meperidine on shivering during delivery under spinal anaesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all women age between 15 and 45 years who are candidates for caesarean section and signed informed consent are eligible to join the study. Exclusion criteria: any contra indication for R/A and those who are sensitive to opioid.

Age
From **15 years** old to **45 years** old
Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **78**

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

Bushehr University of Medical Sciences Ethics
Committee

Street address

Bushehr, Bushehr University of Medical Sciences

City

Bushehr

Postal code

Approval date

2012-12-03, 1391/09/13

Ethics committee reference number

B-91-14-5

Health conditions studied

1

Description of health condition studied

Shivering after delivery

ICD-10 code

O99.8

ICD-10 code description

Other specified diseases and conditions complicating
pregnancy, childbirth and the puerperium

Primary outcomes

1

Description

Post spinal shivering

Timepoint

60 minute

Method of measurement

observation

Secondary outcomes

1

Description

Post operative nausea and vomiting

Timepoint

45 minute

Method of measurement

Observation

Intervention groups

1

Description

Control group received 12.5 mg bupivacaine 0.05,
intratechaly plus 12.5 mg pethidine, intratechaly up to 3
cc

Category

Treatment - Drugs

2

Description

Intervention group receive 12.5 mg bupivacaine 0.05,
intratechaly plus 0.5 cc of normal saline up to 3 cc plus
12.5 mg pethidine, intravenously

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalig Fars hospital

Full name of responsible person

Abdolreza Najafianaraki

Street address

Bushehr University of Medical Sciences

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Dr. Majid Asadi

Street address

Bushehr University of Medical Sciences, Bushehr
City
Bushehr
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bushehr 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
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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