

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 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

Email address

najafianaraki@bpums.ac.ir

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,
intrathecal plus 12.5 mg pethidine, intrathecal up to 3
cc

Category

Treatment - Drugs

2**Description**

Intervention group receive 12.5 mg bupivacaine 0.05,
intrathecal 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
Bushehr University of Medical Sciences
Full name of responsible person
Dr Abdolreza Najafianaraki
Position
Assistant Professor
Other areas of specialty/work
Street address
bushehr university of medical science
City
Bushehr
Postal code
Phone
+98 77 1252 6801
Fax
Email
dr.najafianaraki@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person

Dr Abdolreza Najafianaraki
Position
Assistant professor
Other areas of specialty/work
Street address
Bushehr university of medical science
City
Bushehr
Postal code
Phone
+98 77 1252 6801
Fax
Email
dr.najafianaraki@gmail.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Dr. Abdolreza Najafi Anaraki
Position
Assistant Professor
Other areas of specialty/work
Street address
Bushehr-Bushehr University of Medical Sciences
City
Bushehr
Postal code
Phone
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