

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of different intratechal pethidine on shivering after caesarian surgery

Protocol summary

Summary

After getting the approval of the local committee of ethics in Bushehr university of medical sciences 160 patients ASA 1 and 2 age between 15 and 50 who are candidates for caesarean section and signed informed consent were randomly allocated into four groups. One control group and 3 intervention groups. Group 1 received 10 mg bupivacaine Intratechal, group 2 received 0.2 mg/kg pethidine plus 10 mg bupivacaine Intratechal up to 2 cc, group 3 received 0.3 mg/kg pethidine plus 10 mg bupivacaine Intratechal up to 2 cc, and group 4 received 0.4 mg/kg pethidine plus 10 mg bupivacaine Intratechal up to 2 cc. Shivering, hemodynamic change, nausea and vomiting and pain will be recorded and compared among the study groups. The level of anesthesia in all four groups are T4. The site of needle insertion is T4-T5 by gauge number 24. The monitoring in the four 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

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904101936N3**

Registration date: **2010-10-15, 1389/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-15, 1389/07/23

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

Research committee of university of medica science

Expected recruitment start date

2010-08-22, 1389/05/31

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of different intratechal pethidine on shivering after caesarian surgery

Public title

The effect of different intratechal pethidine on shivering after caesarian surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: All women age between 15 and 50 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 **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **160****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of bushehr medical science

Street address

Siraf avenue

City

Bushehr

Postal code

Iran

Approval date

2010-07-01, 1389/04/10

Ethics committee reference number

BP/20/18/3/10587

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

Shivering after spinal anesthesia

ICD-10 code

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ICD-10 code description

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

Post spinal shivering

Timepoint

90 minute

Method of measurement

observation

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

Post operative nausea and vomiting

Timepoint

90 minute

Method of measurement

observation

2**Description**

Hemodynamic change (BP Change)

Timepoint

90 minute

Method of measurement

NIBP monitoring

3**Description**

Core temperature change

Timepoint

90 minute

Method of measurement

core temperature monitoring

4**Description**

Apgar score of neonate

Timepoint

In minute 5 and 10

Method of measurement

Observation

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

Intratechal injection of 0.2 mg/kg pethidine plus lidocaine

Category

Prevention

2**Description**

intratechal injection of lidocaine 100 mg two cc

Category

Prevention

3**Description**

intratechal injection of 0.3 mg/kg of pethidine plus lidocaine

Category

Prevention

4

Description

Intratechal injection of 0.4 mg/kg pethidine plus lidocaine

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bentolhoda hospital

Full name of responsible person

Dr Najafi Anaraki

Street address

Fateme zahra hospital

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research committee of medical science

Full name of responsible person

Dr Asadi

Street address

Siraf avenue

City

Bushehr

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research committee 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bushehr university of medical science

Full name of responsible person

Dr Najafi Anaraki

Position

Assistant professor

Other areas of specialty/work

Street address

Siraf avenue

City

Bushehr

Postal code

Phone

+98 912 313 3519

Fax

Email

ARNA566@YAHOO.COM

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Bushehr university of medical science

Full name of responsible person

Dr Najafi Anaraki

Position

Assistant professor

Other areas of specialty/work

Street address

Siraf avenue

City

Bushehr

Postal code

Phone

+98 912 313 3519

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