

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Study Between the effect of cold and warm Intra techal Bupivacaine on shivering in caesarian surgery

Protocol summary

Summary

Patients will randomly assign into two equal groups for spinal anesthesia according to numbers inserted in sealed envelopes. Before performing the spinal anesthesia, patients will be under standard monitoring and receive IV lactated Ringer's solution 10 ml/kg. During anesthesia, oxygen is given, and patients will cover with drapes but not actively be warm. All fluids will warm to 37°C. The patients will divide equally into two groups. (n=39). Group A heavy cold bupivacaine up to 2 milliliter plus 10 micrograms of fentanyl, Group B warm bupivacaine up to 2 milliliter plus 10 micrograms of fentanyl, Spinal anesthesia will perform in sitting position at the L4-5 inter space with a mid line approach by using a 25-gauge Quincke needle. Solutions prepare by another anesthesiologist so that the anesthesiologist performing the spinal block is blind of which drug will be injected. After spinal injection, parturient will be placed supine with left uterine displacement. Shivering and other data

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106271936N6**

Registration date: **2011-06-29, 1390/04/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-06-29, 1390/04/08

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

2011-07-23, 1390/05/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study Between the effect of cold and warm Intra techal Bupivacaine on shivering in caesarian surgery

Public title

Comparative Study Between the effect of cold and warm Intra techal Bupivacaine on shivering in caesarian surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Parturient (ASA physical status I or II) age between 18 till 40 scheduled for no emergent cesarean delivery under spinal anesthesia and signing the informed consent Exclusion criteria: Contraindications to regional anesthesia; hypersensitivity to amide local anesthetics; history of headache and

severe preeclampsia
Age
From **18 years** old to **40 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
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1
Ethics committee
Name of ethics committee
Bushehr University of Medical Sciences
Street address
Siraf avenue
City
Bushehr
Postal code
Approval date
2010-12-08, 1389/09/17
Ethics committee reference number
34454/3/18/20/دپ

Health conditions studied

1
Description of health condition studied
Shivering afer spinal anesthesia
ICD-10 code
O74.9
ICD-10 code description
Complication of anaesthesia during labour and delivery, unspecified

Primary outcomes

1
Description

Post operative shivering
Timepoint
Till 120 mimute after surgery
Method of measurement
Observation

Secondary outcomes

1
Description
Nausea and vomiting after surgery
Timepoint
Till 120 minutes after surgery
Method of measurement
Observation

Intervention groups

1
Description
Warm bupivacaine(amid local anesthetic) that hold(in the room) out of refrigerator (%0/5) up to 2 milliliter will be injected Intratechaly once
Category
Prevention

2
Description
Cold bupivacaine(amid local anesthetic) that holdin the refrigerator (%0/5) up to 2 milliliter will be injected Intratechaly once
Category
Prevention

Recruitment centers

1
Recruitment center
Name of recruitment center
Bentolhoda hospital
Full name of responsible person
Dr Najafi Anaraki
Street address
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
School of Medicine, Bushehr University of Medical

Sciences
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 Sciences
Full name of responsible person
Dr. Najafi Anaraki
Position
Assistant professor
Other areas of specialty/work
Street address
Bushehr University of Medical Sciences
City
Bushehr

Postal code
Phone
+98 77 1354 0088
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. Najafi Anaraki
Position
Assistant professor
Other areas of specialty/work
Street address
City
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