

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The comparative effect of intravenous midazolam and sufentanyl on shivering in cesarean delivery

Protocol summary

Summary

After getting the approval of the local committee of ethics in Bushehr University of Medical Sciences, 300 patients ASA 1 and 2 age between 15 and 45 years old who are candidates for caesarean section and signed informed consent, were randomly allocated into three groups. One control group and 2 intervention groups. Group 1 received placebo after delivery of fetus, group 2 received midazolam 0.2 mg/kg after delivery of fetus and group 3 received 0.1 mg/kg sufentanyl. Shivering, hemodynamic change, nausea and vomiting will be recorded and compared among the study groups. 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: **IRCT201407191936N13**

Registration date: **2014-08-03, 1393/05/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-03, 1393/05/12

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

2014-08-01, 1393/05/10

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparative effect of intravenous midazolam and sufentanyl on shivering in cesarean delivery

Public title

The comparative effect of intravenous midazolam and sufentanyl on shivering in cesarean delivery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all women age between 15 and 45 years old 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 midazolam or sufentanyl.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 300

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

Street address

Bushehr University of Medical Sciences, Siraf avenue

City

Busheher

Postal code

Approval date

2013-12-01, 1392/09/10

Ethics committee reference number

B-92-15-14

Health conditions studied

1

Description of health condition studied

Shivering after spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Shivering after cesarian delivery

Timepoint

Minutes 15, 30 and 60

Method of measurement

Observation

Secondary outcomes

1

Description

Patients satisfaction

Timepoint

Before discharge

Method of measurement

Question

Intervention groups

1

Description

In control group patient receive 2 milliliter of sterile water as placebo after delivery of fetus

Category

Treatment - Drugs

2

Description

In intervention group 1 patient receive 0/02 mg per kg Midazolam plus strile water up to two milliliter after delivery of fetus

Category

Treatment - Drugs

3

Description

In intervention group 2 patients receive 0/1 mcg per kg Sufentanyl plus strile water up to two milliliter after delivery of fetus

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadayee Khalig Fars hospital

Full name of responsible person

Dr. Abdolreza Najafi Anaraki

Street address

Busheher Borj

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Committee Bushehr University of Medical Sciences

Full name of responsible person

Dr Majid Asadi

Street address

Bushehr University of Medical Science- 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 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 Najafi Anaraki

Position

Associated professor

Other areas of specialty/work

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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