

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effect of midazolam, fentanyl and placebo on hemodynamic changes caused by spinal blocks in pregnant women undergoing cesarean section referred to valiasr hospital

Protocol summary

Summary

The aim of this study is to compare the effect of midazolam and fentanyl with placebo on hemodynamic changes caused by spinal analgesia in pregnant women undergoing cesarean section referred to Valiasr hospital. It's a triple blind interventional study which pregnant women undergoing cesarean section will be enrolled in. Patients will randomly divide into three groups: The first group: injection of 1 mg midazolam (diluted in 1 ml) The second group: injection of 50 micrograms of fentanyl (1 ml) The third group: injections of placebo (1 ml of distilled water) Major inclusion criteria: women undergoing cesarean section Major exclusion criteria: drop in the fetal heart rate; sensitivity to fentanyl and midazolam.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704085225N7**

Registration date: **2017-05-10, 1396/02/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-10, 1396/02/20

Registrant information

Name

Seyed mohammad Mireskandari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2261 8931

Email address

mireskandari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of midazolam, fentanyl and placebo on hemodynamic changes caused by spinal blocks in pregnant women undergoing cesarean section referred to valiasr hospital

Public title

Comparison of the effect of midazolam, fentanyl and placebo on hemodynamic changes caused by spinal anesthesia

Purpose

Supportive

Inclusion/Exclusion criteria

Major inclusion criteria: women undergoing cesarean section Major exclusion criteria: drop in the fetal heart rate; sensitivity to fentanyl and midazolam.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 105

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Approval date

2017-04-18, 1396/01/29

Ethics committee reference number

IR.TUMS.REC.1396.2930

Health conditions studied

1

Description of health condition studied

Cesarean Section

ICD-10 code

082

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Diastolic blood pressure

Timepoint

Before induction of anesthesia, after induction of spinal anesthesia in minutes 1-2-3-4-5-10-15-20-25

Method of measurement

using Sphygmomanometer in mmHg

2

Description

Systolic blood pressure

Timepoint

Before induction of anesthesia, after induction of spinal anesthesia in minutes 1-2-3-4-5-10-15-20-25

Method of measurement

using Sphygmomanometer in mmHg

3

Description

heart beat

Timepoint

Before induction of anesthesia, after induction of spinal anesthesia in minutes 1-2-3-4-5-10-15-20-25

Method of measurement

Based on the number of beats per minute on heart rate monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intravenous injection of 1 mg midazolam (diluted in 1 ml)

Category

Other

2

Description

Intravenous injection of 50 micrograms of fentanyl (1 ml)

Category

Other

3

Description

Intravenous placebo included (1 ml of distilled water)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Seyed Mohammad Mireskandari

Street address

Valiasr Hospital, Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Science

Full name of responsible person

Dr. Masoud Yoonesian

Street address

Central department of Tehran University of Medical Sciences, Intersection of Keshavarz blvd. and Qods St.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tehran University 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**Name of organization / entity**

Valiasr Hospital

Full name of responsible person

Dr Seyed Mohammad Mireskandari

Position

Anesthesiologist

Other areas of specialty/work**Street address**

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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