Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Phone

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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
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Person responsible for updating data

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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