Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Comparative Study on the Effect of Combined Fentanyl and Midazolam with Propofol Infusion on Blood Pressure and Heart Rate and Satisfaction of Cesarean Patients under Spinal Anesthesia

Protocol summary

Summary

Objective: To compare the effect of combination of fentanyl and midazolam with propofol infusion on blood pressure and heart rate and satisfaction of patients with cesarean section under spinal anesthesia. Design: Non-random- Double-blind (patients and researchers no knowledge about drugs are used), uncontrolled, single-centered, stage two Clinical trials Study population: Pregnant mothers who are selective and non-emergency for referral for cesarean section surgery and nominate spinal anesthesia Main criteria for entering the study: Pregnant mothers who are selective and non-emergency candidates for cesarean section Outcome criteria: having blood pressure, taking blood pressure lowering drugs, for maintaining hemodynamic status using drugs that increase blood pressure and heart rate Sample size: 200 Intervention patients or interventions: intravenous fentanyl and midazolam infusion and propofol infusion to cesarean section under spinal anesthesia, spinal anesthesia with lidocaine 5% plus fentanyl Intervention Time: Approximately 6 months Initial Outcome: It is expected that this study will be a better way to both cost and increase maternal satisfaction, as well as reduce stress and mental stress and mother's anxiety in the operating room.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701277745N6**
Registration date: **2017-07-07, 1396/04/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-07, 1396/04/16

Registrant information

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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Deputy of Research and Technology of Yasuj University of Medical Sciences

Expected recruitment start date

2016-11-30, 1395/09/10

Expected recruitment end date

2017-05-31, 1396/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study on the Effect of Combined Fentanyl and Midazolam with Propofol Infusion on Blood Pressure and Heart Rate and Satisfaction of Cesarean Patients under Spinal Anesthesia

Public title

Spinal anesthesia in patients with cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion: Pregnant mothers who come to the operating room for non-emergency surgery to undergo surgery. Exclusion: Patients with a history of diabetes, addiction, high blood pressure or antihypertensive drug use, and also at the time of surgery for maintaining hemodynamic status using drugs that increase blood pressure and heart rate

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The condition of the patient's comfort and forgiveness is examined from the incidents occurring in the operating room and during the operation of the cesarean section.

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Deputy of Research and Technology

Street address

Yasuj University of Medical Sciences

City

Yasuj

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.YUNS.REC.1395.221

2

Ethics committee

Name of ethics committee

Deputy of Research and Technology

Street address

YUMS

City

Yasuj

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.YUMS.REC.1395. 221

Health conditions studied

1

Description of health condition studied

Spinal Anesthesia in pregnant patient

ICD-10 code

XV

ICD-10 code description

094-099

Primary outcomes

1

Description

heart rate and blood pressure

Timepoint

The patient's arrival time to the operating room, before the spinal anesthesia, every 10 minutes of badness for spinal anesthesia up to 60 minutes

Method of measurement

Using a blood pressure monitor and heart rate monitor

Secondary outcomes

1

Description

Satisfaction and a pleasant feeling by the mother

Timepoint

After the surgery and recovery time

Method of measurement

The question of patient

Intervention groups

1

Description

Spinal anesthesia: Lidocaine 5% at a dose of 75 mg at the start of C/S plus 50 micro-gram Fentanyl Propofol: was infused at a rate of 8 mg per Kg/h Fentanyl was infused at a rate of 0.5 micrograms per kilogram per hour plus midazolam at 0.05 mg per kilogram per hour

Category

Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Sajjad Hospital
Full name of responsible person
Dr. Afshin Mansourian
Street address
City
Yasuj

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Research and Technology
Full name of responsible person
Dr Hossein Ariad
Street address
YUMS
City
Yasuj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Research and Technology
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Deputy of Research and Technology
Full name of responsible person
Dr Hossein Ariad
Street address
YUMS
City
Yasuj
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
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Deputy of Research and Technology
Proportion provided by this source
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

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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