Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of Intravenous Midazolam with Dexmedetomidine Infusion on Sedation and Duration of Spinal Anesthesia with Bupivacaine For Cesarean Section

Protocol summary

Summary

Intravenous dexmedetomidine when used justr after spinal anaesthesia has many desirable effects such as adequate sedation, longer sensory-motor blockade, prolonged postoperative analgesia. The objectives of this study are to compare and evaluate the efficacy of intravenous dexmedetomidine premedication with midazolam on postoperative analgesia and sedation in patients undergoing cesarean section under bupivacaine spinal block. In this randomized double blind clinical trial, 70 ASA Class I/II patients with written informed consent, undergoing elective cesarean section under spinal anesthesia will divide into two groups of 35 each. In all patients subarachnoid block will perform with 3 ml of 0.5% hyperbaric bupivacaine, sensory and motor blockade will assesse. Immediately after umbilical cord clamping patients in group one will receive dexmedetomidine 1 µg/kg intravenously, whereas patients in group two will receive midazolam 0.03 mg/kg. The level of sedation will evaluate using Ramsay level of sedation scale intraoperatively and postoperatively every 15 mins. Blood pressure and heart rate will assess. The drugs will be prepared in covered syringes and will be injected blindly with an anesthesiologist who has performed the spinal block. Another person who is blinded to the drug injection will control intra and postoperative. Data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111410765N12**
Registration date: **2016-12-07, 1395/09/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-07, 1395/09/17

Registrant information

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Recruitment status

Recruitment complete

Funding source

Research center,Tabriz University of Medical Sciences

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-07-23, 1396/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Intravenous Midazolam with Dexmedetomidine Infusion on Sedation and Duration of Spinal Anesthesia with Bupivacaine For Cesarean Section

Public title

Sedation and Duration of Spinal Anesthesia For Cesarean Section with IV Midazolam or Dexmedetomidine

Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: Parturients candidate for elective cesarean section; ASA Class I & II;patients will give written informed consent Exclusion criteria: Parturients with ASA Class III or higher; spinal anesthesia contraindications; Diabetics; preterm labor;hypertensive parturients; preeclampsia and eclampsia; hypotension; bradycardia; drug allergy; alcohol abuse; patients with cardiovascular; respiratory, renal; hepatic diesease ´
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: **70**
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
Vice chancellor for research, Tabriz University of Medical Sciences
Street address
Golgasht Ave, Tabriz University of Medical Scienses,
City
Tabriz
Postal code
Approval date
2016-08-29, 1395/06/08
Ethics committee reference number
IR.TBZMED.REC.1395.570

Health conditions studied

1

Description of health condition studied
Adverse effect of drug
ICD-10 code
T88.9
ICD-10 code description
Complication of surgical and medical care, unspecified

Primary outcomes

1

Description
Sedation
Timepoint
During surgery and ricovery
Method of measurement
Ramsay sedation score (0-6)

Secondary outcomes

1

Description
Blood pressure
Timepoint
During surgery and recovery
Method of measurement
Non invasive

Intervention groups

1

Description
Intervention Group: The patients will be received 1 µg/kg of dexmedetomidine in 20 cc normal saline intravenously by over 10 min.
Category
Treatment - Drugs

2

Description
Patients will be received midazolam 0.03 mg/kg intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Obstetric and Gynecologic Hospital
Full name of responsible person
Sousan Rasouli
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Al-Zahra Hospital, Sought Artesh Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Elahe Madarek
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Vice Chancellor for Research, Building No. 2 Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

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Name of organization / entity
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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