

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 just 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 assess. 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

Name

Sousan Rasooli

Name of organization / entity

Alzahra hospital/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

rasoolis@tbzmed.ac.ir

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 disease

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 Sciences,

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 recovery

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

Street address

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

Street address

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

Contact

Name of organization / entity

Reaserch center, Tabriz University of Medical
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Full name of responsible person

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Position

Professor of Anesthesiology

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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