

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

##### City

Tabriz

## 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  
Sciences

**Full name of responsible person**

Sousan Rasouli

**Position**

Professor of Anesthesiology

**Other areas of specialty/work**

**Street address**

Al-Zahra Hospital, South Artesh Street

**City**

Tabriz

**Postal code**

**Phone**

+98 415539161

**Fax**

**Email**

Rasooli\_s@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Reaserch Center, Tabriz University of Medical  
Sciences

**Full name of responsible person**

Sousan Rasouli

**Position**

Professor of Anesthesiology

**Other areas of specialty/work**

**Street address**

Al-Zahra Hospital, South Artesh Street

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3553 9161

**Fax**

**Email**

Rasooli\_s@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Reaserch center, Tabriz University of Medical  
Sciences

**Full name of responsible person**

Sousan Rasouli

**Position**

professor of Anesthesiology

**Other areas of specialty/work**

**Street address**

Alzahra Hospital, South Artesh Ave

**City**

Tabriz

**Postal code**

**Phone**

+98 41 3553 9161

**Fax**

+98 41 3556 6449

**Email**

Rasooli\_s@yahoo.com

**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*