

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Prevention of Shivering During and Post Cesarean Section with Spinal Anesthesia

#### Protocol summary

##### Summary

Shivering is one of the most common intra and postoperative problems with a 20%-60% reported incidence. In addition to patient's discomfort, intra and postoperative hypothermia and shivering interfere with patient's monitoring and can increase oxygen consumption and CO<sub>2</sub> production. Recently  $\alpha$ -2 agonists like dexmedetomidine due to central hypothalamic thermoregulation have been shown to be effective in the prevention of intra and postoperative shivering. The aim of this study is to evaluate the effect of dexmedetomidine in prevention of shivering in patients undergoing to cesarean section with spinal anesthesia with suggestion that prophylactic administration of this agent can prevent intra and postoperative shivering or reduce its severity. After obtaining written informed consent for entering to study, 70 pregnant patients scheduled for cesarean section will enrolled in two groups of 35 and receive spinal anesthesia. Case or dexmedetomidine group will be administered 1  $\mu$ g/kg dexmedetomidine in 20 ml normal saline immediately after delivery and cord clamping and the control group will receive normal saline as placebo in the same volume. The incidence and severity of intra and postoperative shivering will be checked and recorded according to Crossley and Mahjon scores. Shivering scores equal or higher than 3 will be treated with 0.5 mg/kg IV Meperidine.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016070210765N9**  
Registration date: **2016-12-10, 1395/09/20**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-10, 1395/09/20

##### 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

2016-11-20, 1395/08/30

##### Expected recruitment end date

2017-07-21, 1396/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Prevention of Shivering During and Post Cesarean Section with Spinal Anesthesia

##### Public title

The Effect of Intravenous Dexmedetomidine for Prevention of Shivering During and Post Cesarean Section with Spinal Anesthesia

##### Purpose

Prevention

## **Inclusion/Exclusion criteria**

Inclusion criteria: parturients aged 18-42 years old; patients with ASA class I & II; patients signed informed consent. Exclusion criteria: parturients with ASA class III or high; contraindication for spinal anesthesia; diabetics; preterm labor; hypertension; preeclampsia and eclampsia; allergy; drug or alcohol abuse; cardiovascular disease; respiratory disease; renal and hepatic disease; hypo or hyperthermic disease.

## **Age**

From **18 years** old to **42 years** old

## **Gender**

Female

## **Phase**

2-3

## **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**

Tabriz University of Medical Sciences, Golgasht Ave.

##### **City**

Tabriz

##### **Postal code**

#### **Approval date**

2016-07-04, 1395/04/14

#### **Ethics committee reference number**

IR.TBZMED.REC.1395.319

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Hypothermia following anaesthesia

#### **ICD-10 code**

T88.5

## **ICD-10 code description**

Other complications of anaesthesia(Hypothermia following anaesthesia)

## **Primary outcomes**

### 1

#### **Description**

severity of shivering

#### **Timepoint**

Intra and postoperative

#### **Method of measurement**

Crossley and Mahjon scale

## **Secondary outcomes**

### 1

#### **Description**

Mepidine requirements

#### **Timepoint**

Intra and postoperative

#### **Method of measurement**

Crossley and Mahjon scale

## **Intervention groups**

### 1

#### **Description**

Intervention or dexmedetomidine group will be administered 1 µg/kg dexmedetomidine in 20 ml normal saline immediately after delivery and cord clamping.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group will receive normal saline as placebo in the same volume.

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Alzahra Hospital

##### **Full name of responsible person**

Sousan Rasouli

##### **Street address**

Alzahra Hospital, South Artesh Ave, Tabriz

##### **City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research center, Tabriz University of Medical Sciences

**Full name of responsible person**

Elahi Madarek

**Street address**

Vice chancellor for reaserch, No 2, Central bulding of Tabriz University of Medical Sciences, Golgasht Ave

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research center, 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Full name of responsible person**

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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*