

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of the effect of preoperative single dose dexmedetomidine with midazolam on Postoperative shivering after total intravenous anesthesia in ambulatory gynecologic surgeries

#### Protocol summary

##### Summary

The goal of this study is to compare the effect of preoperative administration of a single dose dexmedetomidine with midazolam for prevention of postoperative shivering in patients who received total intravenous anesthesia with remifentanyl for outpatient gynecologic surgeries. In this randomized double blind clinical trial, 70 ASA classes I & II patients who were obtained written informed consent candidate for outpatient surgery will be divided to two groups of 35. In all patients, baseline blood pressure, heart rate, Sao<sub>2</sub> and body temperature will be noted. Operative room and injected solutions temperature will be the same. All patients will receive anesthesia with loading dose of 2.5 mg/kg Propofol, then infusion of propofol and Remifentanyl (0.5 µg/kg/min) will be continued. Group one will be administered Dexmedetomidine 1 µg/kg in 20 ml normal saline over 10 minute and 1 ml normal saline immediately before operation. Group two will receive normal saline in the same volume (as placebo), and 1 mg midazolam. All medications will be prepared in covered syringes and will be injected blindly with an anesthesiologist. The incidence and severity of postoperative shivering will be checked and recorded according to Crossley scores. Shivering scores equal to or higher than 3 will be treated with 25 mg IV meperidine. Data will be analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017022410765N13**  
Registration date: **2017-05-18, 1396/02/28**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-05-18, 1396/02/28

##### 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

Investigator

##### Expected recruitment start date

2017-03-21, 1396/01/01

##### 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 preoperative single dose dexmedetomidine with midazolam on Postoperative shivering after total intravenous anesthesia in ambulatory gynecologic surgeries

##### Public title

Effect of dexmedetomidine on postoperative shivering

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: patients candidate for gynecologic outpatient surgeries; aged 18 - 45 years; patients will give written informed consent; patients with ASA class I & II Exclusion criteria: patients with ASA class III or higher; cardiovascular diseases or heart block; bradycardia; hypertension or hypotension; neurological diseases; renal and hepatic diseases; respiratory diseases; diabetics; patients who receive alpha 2 Agonists

## Age

From **18 years** old to **45 years** old

## Gender

Female

## Phase

2

## 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

Using a computer-generated randomization table, patients were randomized to one of two groups

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

##### Street address

Golgasht Ave, Tabriz University of Medical Sciences,

##### City

Tabriz

##### Postal code

#### Approval date

2017-01-23, 1395/11/04

#### Ethics committee reference number

IR.TBZMED.REC.1395.1149

## Health conditions studied

### 1

#### Description of health condition studied

Shivering

#### ICD-10 code

T88.5

#### ICD-10 code description

Other complications of anaesthesia Hypothermia following anaesthesia

## Primary outcomes

### 1

#### Description

Incidence of postoperative shivering

#### Timepoint

Every 15 minutes immediately post onset of spinal anesthesia until one hour post anesthesia

#### Method of measurement

Crossley and Mahjon score

## Secondary outcomes

### 1

#### Description

Sao2

#### Timepoint

every 15 minutes

#### Method of measurement

Paloximetry

## Intervention groups

### 1

#### Description

Intervention group: The patients of this group will be receive single dose of dexmedetomidine 1 µg/kg in 20 ml normal saline Iv over 10 minutes and 1 ml placebo immediately before operation

#### Category

Treatment - Drugs

### 2

#### Description

Control group: The patients of this group will be receive 1 mg midazolam and 20 ml normal saline over 10 minutes IV as placebo immediately before operation.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra Obstetric and Gynecologic Hospital

##### Full name of responsible person

Sousan Rasouli

**Street address**

AlZahra Hospital, Sought Artesh Street

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Tabriz University of Medical Sciences

**Full name of responsible person**

Hasan Soleimanpour

**Street address**

Recerch Center, 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**

Vice Chancellor for research of 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**

Elahe Madarek

**Position**

Professor of Anesthesiology

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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*