# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Comparing the effect of Dexmedetomidine-Paracetamol combination and placebo in prevention of postoperative pain in patients undergoing cesarean delivery with spinal anesthesia

## Protocol summary

**Study aim**
Reduction of pain in cesarean delivery patients with spinal anesthesia using dexmedetomidine and paracetamol

**Design**
A total of 100 patients that meet the inclusion criteria will be selected and then will be assigned to the intervention and control groups by block randomization method with blocks of size 2. The study is a randomized, double-blind, placebo-controlled clinical trial.

**Settings and conduct**
A hundred pregnant women candidates for cesarean delivery who visit the operating room of Al-Zahra Women's Hospital in Tabriz will participate in this study. In this study, which is a two-way blind clinical trial, patients will be randomly allocated to one of two groups of 50 patients including Dexamethasone-Paracetamol, and the normal saline group (as placebo). There will be two types of envelopes. Envelope A contains syringes containing Dexamethasone and Paracetamol, and envelope B contains syringes containing normal saline (placebo). Each patient will receive these envelopes by an anesthesiologist who is unaware of the type of medication and will give envelopes to the patients based on codes A or B.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Pregnant women between the ages of 18 and 60 years old; ASA class one and two; candidates for elective cesarean section or spinal anesthesia. Exclusion criteria : Sensitivity to the studied compounds; Mental disease; Patients with cardiovascular, pulmonary, liver, kidney and ...disease; Multiple pregnancy.

**Intervention groups**
Intervention group: In this group 1 gr paracetamol and 1 mg / kg dexmedomidine in 100 ml normal saline are infused 15 minutes before the end of the surgery. Control group: In this group only normal saline (as placebo) which is as the same as the drug in the intervention group in shape and color will be prescribed 15 minutes before the end of the surgery.

**Main outcome variables**
Postoperative pain

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20110712007013N27**
Registration date: **2020-04-08, 1399/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-08, 1399/01/20**
Update count: **0**

**Registration date**
2020-04-08, 1399/01/20

**Registrant information**

**Name**
Simin Atashkhoei
**Name of organization / entity**
Tabriz University of Medical Siences
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-11-22, 1398/09/01

**Expected recruitment end date**

2020-05-21, 1399/03/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparing the effect of Dexmedetomidine-Paracetamol combination and placebo in prevention of postoperative pain in patients undergoing cesarean delivery with spinal anesthesia

**Public title**
The effect of dexmedetomidine and paracetamol on postoperative pain of cesarean section with spinal anesthesia

**Purpose**
Prevention

**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Pregnant women between the ages of 18 and 60 years old ASA class one and two Candidates for elective cesarean section or spinal anesthesia
**Exclusion criteria:**
Sensitivity to the compounds used for intervention group Mental illness Patients with cardiovascular, pulmonary, liver and kidney and ...disease Multiple pregnancy Urgent cesarean

**Age**
From **18 years** old to **40 years** old

**Gender**
Female

**Phase**
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**
Target sample size: **100**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients wishing to participate in the study who meet the inclusion criteria will be selected through convenient sampling and then randomly assigned to two control and intervention groups using Randlist software

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
The anesthesiologist who is responsible for the patients management to induce anesthesia will administer the medicine(s) via coded syringes which have been prepared previously and therefore he/she will not be aware of the injected drug. Meanwhile the anesthesia nurse who is responsible for collection of patients' information and study variables and is unaware of the administered drug will fill the check- list during surgery and in the recovery room. Also the patient is unaware of the injected medicine.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Tabriz University of Medical Sciences
**Street address**
Vice chancellor for research, Golgasht Street
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5183915881

**Approval date**
2019-11-25, 1398/09/04

**Ethics committee reference number**
IR.TBZMED.REC.1398.915

## Health conditions studied

**1**

**Description of health condition studied**
Acute postoperative pain

**ICD-10 code**
G89.18

**ICD-10 code description**
Other acute postprocedural pain

## Primary outcomes

**1**

**Description**
Pain

**Timepoint**
At post-anesthesia care unit and at 1, 3, 6, 12 and 24 hours after surgery

**Method of measurement**
Visual analogue scale (VAS) (from 0= no pain to 10= severe pain)

## Secondary outcomes

**1**

**Description**

Overall dose of postoperative analgesic

**Timepoint**

At post-anesthesia care unit and during 24 hours after surgery

**Method of measurement**

Number and amount of medication by mg, based on patient's record

## Intervention groups

### 1

**Description**

Intervention group: In this group 1 gr Paracetamol and 1 mg/kg Dexmedomidine in 100 ml normal saline is infused 15 minutes before the end of the surgery.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: In this group only normal saline (as placebo) which is as the same as the drug in the intervention group in shape and color will be prescribed 15 minutes before the end of the surgery.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Al-Zahra Hospital

**Full name of responsible person**

Dr. Simin Atashkhoyi

**Street address**

Al-Zahra Hospital , South Artesh street, Tabriz

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satashkhoyi@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr Abolghasem Jouyban

**Street address**

Research and Technology deputy, third floor, the headquarter building No 2, Tabriz University of Medical Sciences, Golgasht street, Tabriz

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**Email**

research-vice@tbzmed.ac.ir

**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**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Simin Atashkhoyi

**Position**

Anesthesiologist/Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
A portion of the data that represents the final outcome

**When the data will become available and for how long**
starting 6 months after publication

**To whom data/document is available**
All Physicians and residents of the Anesthesia field

**Under which criteria data/document could be used**
There will be no specific limitation to the utilization of the data.

**From where data/document is obtainable**
Dr .Simin Atashkhoei; Al-Zahra Hospital; South Artesh Street; Tabriz; East Azarbaijan; Islamic Republic of Iran. Phone number: +98 41 1553 9161; Fax number: +98 41 1556 6449. Email address: siminatashkhoii@yahoo.com

**What processes are involved for a request to access data/document**
Being approved by the Research and Technology deputy at first

**Comments**