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)
Phone
+98 41 3333 3806
Email address
atashkhoii@tbzmed.ac.ir

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Phone

+98 41 3553 9161

Fax

+98 41 3556 6449

Email

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

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Fax

+98 41 3335 7310

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

Street address

Al-Zahra Hospital, South Artesh street, Tabriz

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Fax

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Email

satashkhoyi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Simin Atashkhoyi

Position
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+98 41 3553 9161

Email
satashkhoyi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr. Simin Atashkhoyi

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Fax
+98 41 3553 9161

Email
satashkhoyi@gmail.com

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