

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jul 2026

### Comparison the effect of interathecal injection of Dexmedetomidine plus Bupivacanie and Bupivacanie on maternal hemodynamic parameters and pain; and neonatal APGAR and arterial blood gases of women undergoing cesarean delivery under spinal anesthesia

#### Protocol summary

##### Study aim

Comparison the effect of interathecal injection of Dexmedetomidine plus Bupivacanie and Bupivacanie on maternal hemodynamic parameters and pain; and neonatal APGAR and arterial blood gases of women undergoing cesarean delivery under spinal anesthesia

##### Design

Parallel double blinded randomized controlled clinical trial

##### Settings and conduct

Selecting 82 pregnant women candidate for elective cesarean delivery under spinal anesthesia at 5 Azar tertiary hospital affiliated to Golestan university of medical sciences and assigning them to two groups by block balanced randomization.

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Pregnant women with repeated cesarean delivery, and more than 39 gestational age; Age between 18 to 40 years old; Candidate for elective cesarean delivery underwent spinal anesthesia; American Society of Anesthesiologists (ASA) physical status classification system I and II; Without history of respiratory, cardiovascular and systemic diseases, and cancers; Without history of drug abuse or sedative & hypnotic drugs; Without congenital malformation, and preterm labor; Without history of medication allergy; Without coagulopathy; Hemoglobin level above 10 g/dl. Exclusion Criteria: Use of sedative and hypnotic drugs before surgery; Use of anticoagulants 48 hours before surgery; With psychiatric disorders

##### Intervention groups

Intervention group: Intrathecal injection of 2.5 ml of Bupivacanie 0.5% plus 5 µg of Dexmedetomidine (total volume of 3.0 ml). Control group: Intrathecal injection of 2.5 ml of Bupivacanie 0.5% with half a milliliter of 0.9 % saline (total volume of 3.0 ml)

#### Main outcome variables

Maternal hemodynamic parameters and pain; neonatal APGAR and arterial blood gases

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181107041590N1**

Registration date: **2019-01-05, 1397/10/15**

Registration timing: **prospective**

Last update: **2019-01-05, 1397/10/15**

Update count: **0**

##### Registration date

2019-01-05, 1397/10/15

##### Registrant information

###### Name

Monireh Jahani

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 3232 0370

###### Email address

jahani.mn@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-01-10, 1397/10/20

##### Expected recruitment end date

2019-02-20, 1397/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison the effect of interathecal injection of Dexmedetomidine plus Bupivacanie and Bupivacanie on maternal hemodynamic parameters and pain; and neonatal APGAR and arterial blood gases of women undergoing cesarean delivery under spinal anesthesia

**Public title**

Comparison the effect of Dexmedetomidine plus Bupivacanie and Bupivacanie on maternal hemodynamic parameters and pain; and neonatal APGAR and arterial blood gases

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Pregnant women with repeated cesarean delivery and more than 39 gestational age Age between 18 to 40 years old Candidate for elective cesarean delivery underwent spinal anesthesia American Society of Anesthesiologists (ASA) physical status classification system I and II Without history of asthma, cardiovascular diseases, diabetes, acute and chronic renal failure, deep vein thrombosis, pulmonary embolism, peripheral vascular diseases, preeclampsia, eclampsia, seizure, convulsion, and cancers Without history of drug abuse or sedative & hypnotic drugs Without congenital malformation Without history of airway problems and systemic diseases, and preterm labor Without history of medication allergy Without coagulopathy Hemoglobin level above 10 g/dl Normal level of clotting time (CT), bleeding time (BT), prothrombin time (PT), partial thromboplastin time (PTT), and international normalized ratio (INR) Having at least two clinical visit with obstetrician and one blood test and 2 control sonography during pregnancy in pregnancy record Filling the informed consent form

**Exclusion criteria:**

Use of sedative and hypnotic drugs before surgery Use of anticoagulants 48 hours before surgery With psychiatric disorders

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

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**Target sample size: **82****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block balanced randomization method will be used. Randomization sequence will be generated by free website available from: [www.randomization.com](http://www.randomization.com), in which letter A and B will be considered for intervention and control group, respectively. For random allocation concealment, cards containing blocks will be inserted in standard envelopes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this double blind study, patient and pain assessor are not aware of allocated groups. Main investigator is not aware of the pain pump content.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Golestan University of Medical Sciences

**Street address**

Hirkan Blvd., Beginning of Shastkola road, Falsafi Educational Campus of Golestan University of Medical Sciences, Gorgan town

**City**

Gorgan

**Province**

Golestan

**Postal code**

4934174515

**Approval date**

2018-11-18, 1397/08/27

**Ethics committee reference number**

IR.GOUMS.REC.1397.181

**Health conditions studied****1****Description of health condition studied**

Cesarean delivery

**ICD-10 code**

O75.82

**ICD-10 code description**

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

## Primary outcomes

### 1

#### Description

Hemodynamic parameters (heart rate and blood pressure)

#### Timepoint

Before and 1, 5, 15, 30 and 60 minute after surgery

#### Method of measurement

Vital-signs monitoring device

## Secondary outcomes

### 1

#### Description

Maternal pain

#### Timepoint

Before and 1, 6, 12 and 24 hours after surgery

#### Method of measurement

Visual analogous scale

### 2

#### Description

Neonatal APGAR

#### Timepoint

1st and 5th minute after birth

#### Method of measurement

APGAR scale

### 3

#### Description

Arterial blood gases

#### Timepoint

After birth

#### Method of measurement

Arterial blood gases analysis

## Intervention groups

### 1

#### Description

Intervention group: Intrathecal injection of 2.5 ml of Bupivacanie 0.5% (Astra Zeneca company, Sweden) plus 5 µg of Dexmedetomidine (Pfizer company, US) (total volume of 3.0 ml)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Intrathecal injection of 2.5 ml of Bupivacanie 0.5% (Astra Zeneca company, Sweden) with half a milliliter of 0.9 % saline (Shahid Ghazi pharmaceutical company) (total volume of 3.0 ml)

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

5 Azar tertiary hospital

##### Full name of responsible person

Monireh Jahani

##### Street address

5th Azar street, 5 Azar tertiary hospital, Gorgan town

##### City

Gorgan

##### Province

Golestan

##### Postal code

4934174515

##### Phone

+98 17 3232 0370

##### Email

jahani.mn@goums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gorgan University of Medical Sciences

##### Full name of responsible person

Dr. Mohammadreza Honarvar

##### Street address

Hirkan Blvd., Beginning of Shastkola road, Falsafi Educational Campus of Golestan University of Medical Sciences, Gorgan town

##### City

Gorgan

##### Province

Golestan

##### Postal code

4934174515

##### Phone

+98 17 3245 1660

##### Email

honarvar@goums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Gorgan 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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Monireh Jahani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

5th Azar street, 5 Azar tertiary hospital, Gorgan town

**City**

Gorgan

**Province**

Golestan

**Postal code**

4934174515

**Phone**

+98 17 3232 0370

**Email**

jahani.mn@goums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Ali Jabbari

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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5th Azar street, 5 Azar tertiary hospital, Gorgan town

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**Phone**

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**Email**

Amir\_a\_72@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Monireh Jahani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**

After making data unrecognizable, all data will be shared.

**When the data will become available and for how long**

Starting in January 2020

**To whom data/document is available**

It will be available for researchers working in academic institutions.

**Under which criteria data/document could be used**

For people who have academic education and those data can be useful for their research

**From where data/document is obtainable**

Dr. Ali Jabbari: Amir\_a\_72@yahoo.com

**What processes are involved for a request to access data/document**

Email to "Amir\_a\_72@yahoo.com" and comment that why he/she wants to access to these data

**Comments**