

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

AgeFrom **18 years** old to **40 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget 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, 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

Street address

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

City

Gorgan

Province

Golestan

Postal code

4934174515

Phone

+98 17 3232 0370

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

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

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