

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison on analgesic and sedative effects of dexmedetomidine and midazolam in patients undergoing cesarean section

Protocol summary

Study aim

Comparison on analgesic and sedative effects of dexmedetomidine and midazolam in patients undergoing cesarean section

Design

Clinical trials with control group, with parallel groups, Blind two-sided, randomized, without control with placebo, single center trial.

Settings and conduct

The drug is injected with Dexmedetomidine or midazolam, or normal saline after the baby is removed and the umbilical cord clam. Amir Al-Momenin Hospital. The participant, the main researcher, health personnel who evaluate the outcomes will not be informed about the grouping of patients and the type of medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women 20 to 40 years; Women candidates for elective cesarean; Repeated cesarean (second to fourth). Exclusion criteria: Preeclampsia patients; Chronic blood pressure; Emergency cesarean; Arrhythmia and heart block; Drug use: calcium blocker, adrenergic receptor blocker, psychoactive drugs.

Intervention groups

Intervention group 1: 0.5 mg / kg doses of dexmedetomidine in 100 ml of normal saline in 10 minutes. Intervention group 2: Midazolam infusion 2 mg per 100 ml of normal saline within 10 minutes. Control group: 100 cc normal saline infusion in 10 minutes.

Main outcome variables

Pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N40**

Registration date: **2019-07-13, 1398/04/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**

Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-21, 1397/05/30

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison on analgesic and sedative effects of dexmedetomidine and midazolam in patients undergoing cesarean section

Public title

Comparison on analgesic and sedative effects of dexmedetomidine and midazolam in patients undergoing cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Women 20 to 40 years Women candidates for elective cesarean Repeated cesarean (second to fourth)

Exclusion criteria:
Preeclampsia patients Chronic blood pressure
Emergency cesarean Arrhythmia and heart block Drug use: calcium blocker, adrenergic receptor blocker, psychoactive drugs

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 3). Using Excel software to generate random number tables.

Blinding (investigator's opinion)
Double blinded

Blinding description
The participant, the main researcher, health personnel who evaluate the outcomes will not be informed about the grouping of patients and the type of medication.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2018-08-21, 1397/05/30

Ethics committee reference number

IR.SEMUMS.REC.1397.123

Health conditions studied

1

Description of health condition studied

Caesarean section

ICD-10 code

O84.2

ICD-10 code description

Multiple delivery, all by caesarean section

Primary outcomes

1

Description

Pain intensity

Timepoint

6 and 12 hours after surgery

Method of measurement

VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: 0.5 mg / kg doses of dexmedetomidine in 100 ml of normal saline in 10 minutes

Category

Diagnosis

2

Description

Intervention group 2: Midazolam infusion 2 mg per 100 ml of normal saline within 10 minutes

Category

Diagnosis

3

Description

Control group: 100 cc normal saline infusion in 10 minutes

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Hospital

Full name of responsible person

Elham Saffarieh

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

City

Semnan

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3514799442

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are20935@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Elham Saffarieh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

Elham Saffarieh

Position

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Person responsible for updating data

Contact**Name of organization / entity**

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Full name of responsible person

Atoosa Naviafar

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

Only available to scholars working in academic institutions.

Under which criteria data/document could be used

In case of relevant studies.

From where data/document is obtainable

Elham Saffarieh, Amir Al-Momenin Hospital, Mostafa Khomeini Blvd. +989123313982

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

-

Comments