Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of intravenous dexmedetomidine on shivering after elective cesarean section under intrathecal anesthesia

Protocol summary

Study aim
Determining of the efficacy of dexmedetomidine in prevention of shivering after intrathecal anesthesia in women undergoing cesarean section

Design
This is a clinical trial study with control group with parallel groups, double-blinded and randomized, which will be conducted on 80 women undergoing cesarean section with intrathecal anesthesia. Assignment of patients to the study groups will be done by block randomization method using blocks of size four.

Settings and conduct
From pregnant women candidate for cesarean section with intrathecal anesthesia referring to Imam Khomeini hospital, Ahvaz, total of 80 patients will be selected and randomly divided into 2 groups. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18 to 35 years; ASA Class I and II; Gravida I and II pregnant women; candidate for elective cesarean section; consent to participate in the study. Non inclusion criteria: history of seizure; severe renal and liver disease; Maternal febrile disorder; coagulation disorder.

Intervention groups
In intervention group, Dexmedetomidine 0.5 µg/kg diluted with normal saline in a volume of 20 cc will be injected at a rate of 120 cc/h during 10 minutes after cord clamping. In the control group, normal saline (20 cc) will be used (instead of Dexmedetomidine) as control.

Main outcome variables
Hemodynamic changes including Heart rate (HR), diastolic blood pressure (DBP), systolic blood pressure and body temperature, shivering and side-effects including nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200107046042N1**
Registration date: **2020-09-01, 1399/06/11**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-01, 1399/06/11**
Update count: **0**

Registration date
2020-09-01, 1399/06/11

Registrant information

Name
Soraya Bayat

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3222 5168

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bayat.s@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2021-02-18, 1399/11/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of intravenous dexmedetomidine on shivering after elective cesarean section under intrathecal anesthesia

Public title
The effect of dexmedetomidine on shivering after cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18 to 35 years ASA Class I and II Gravida I and II pregnant women Candidate for elective cesarean section Consent to participate in the study
Exclusion criteria:
History of seizure Severe renal or liver disease Maternal febrile disorder Coagulation disorder
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups of experimental and control. Assignment of patients to the study groups will be done by block randomization method using blocks of size four.
Blinding (investigator's opinion)
Double blinded
Blinding description
Intervention (receiving dexmedetomidine or normal saline) and patient evaluation will be carried out by a physician who is blinded to both treatment groups. Also patients and statistical analyzer will not know about patient grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2020-06-29, 1399/04/09
Ethics committee reference number
IR.AJUMS.REC.1399.305

Health conditions studied

1

Description of health condition studied
Shivering after cesarean section
ICD-10 code
R68.83
ICD-10 code description
Chills (without fever)

Primary outcomes

1

Description
Ṣhivering
Timepoint
Every 5 minutes until 45 minutes after block
Method of measurement
Chu and Tsai score

2

Description
Body temperature
Timepoint
Before intrathecal anesthesia and every 5 minutes after drug administration for 45 minutes
Method of measurement
Tympanic Thermometer (Micro Life, Madisa Novin Peish Co, Taiwan)

3

Description
Systolic blood pressure
Timepoint
At the beginning of the study (before the intervention) and then every 5 minutes
Method of measurement
Mercury barometer

4

Description
Diastolic blood pressure

Timepoint
At the beginning of the study (before the intervention) and then every 5 minutes
Method of measurement
Mercury barometer

Secondary outcomes

1

Description
Nausea after surgery
Timepoint
Up to 2 hours after the patient entry to recovery
Method of measurement
Presence of nausea based on direct observation and patients report

2

Description
Vomiting after surgery
Timepoint
Up to 2 hours after the patient entry to recovery
Method of measurement
Presence of vomiting based on direct observation and patients report

Intervention groups

1

Description
Intervention group: Dexmedetomidine 0.5 µg/kg (Exir CO., Iran) diluted with normal saline in a volume of 20 cc will be injected at a rate of 120 cc/h during 10 minutes, after cord clamping.
Category
Prevention

2

Description
Control group: Normal saline 20 cc will be injected at a rate of 120 cc/h during 10 minutes after the cord clamping.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Soraya Bayat
Street address
Imam Khomeini Hospital, Azadegan street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Sholeh Nesioonpour
Position
Associate Professor
Latest degree
Specialist
Other areas of specialty/work

Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available