

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)

Phone

+98 61 3222 5168

Email address

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		Medical Sciences	
Public title		Street address	
The effect of dexmedetomidine on shivering after cesarean section		Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.	
Purpose		City	
Prevention		Ahvaz	
Inclusion/Exclusion criteria		Province	
Inclusion criteria:		Khouzestan	
Age between 18 to 35 years ASA Class I and II Gravidia I and II pregnant women Candidate for elective cesarean section Consent to participate in the study		Postal code	
Exclusion criteria:		6135733118	
History of seizure Severe renal or liver disease Maternal febrile disorder Coagulation disorder		Approval date	
Age		2020-06-29, 1399/04/09	
From 18 years old to 35 years old		Ethics committee reference number	
Gender		IR.AJUMS.REC.1399.305	
Female		Health conditions studied	
Phase		1	
3		Description of health condition studied	
Groups that have been masked		Shivering after cesarean section	
- Participant - Outcome assessor - Data analyser		ICD-10 code	
Sample size		R68.83	
Target sample size: 80		ICD-10 code description	
Randomization (investigator's opinion)		Chills (without fever)	
Randomized		Primary outcomes	
Randomization description		1	
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.		Description	
Blinding (investigator's opinion)		Shivering	
Double blinded		Timepoint	
Blinding description		Every 5 minutes until 45 minutes after block	
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.		Method of measurement	
Placebo		Chu and Tsai score	
Not used		2	
Assignment		Description	
Parallel		Body temperature	
Other design features		Timepoint	
Secondary Ids		Before intrathecal anesthesia and every 5 minutes after drug administration for 45 minutes	
empty		Method of measurement	
Ethics committees		Tympanic Thermometer (Micro Life, Madisa Novin Peish Co, Taiwan)	
1		3	
Ethics committee		Description	
Name of ethics committee		Systolic blood pressure	
Ethics committee of Ahvaz Jundishapur University of		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

City

Ahvaz

Province

Khouzestan

Postal code

6193673111

Phone

+98 61 3222 2818

Email

S.bayat.ab@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Ahvaz Jundishapur University of Medical Sciences,
Golestan Blvd.

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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

Street address

Imam Khomeini Hospital, Azadegan street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Soraya Bayat

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

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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