

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation of intrathecal dexmedetomidine effect on core body temperature and shivering during spinal anesthesia for cesarean section

Protocol summary

Summary

Objectives : The aim of this study is to evaluate the effect of intrathecal dexmedetomidine on core body temperature and shivering during spinal anesthesia in patients undergoing elective cesarean section . **Design :** In this double blind , clinical trial 50 patients with American Society of Anesthesiologist physical status I or II who schedule for cesarean section will divide randomly in two equal group. **Setting :** After induction of spinal anesthesia patient will be covered by one layer of surgical drapes over the whole body beside head and neck during the operation and one cotton blanket in post anesthesia care unit. The temperature of operating room and post anesthesia care will be maintained in the range of 22-26 °C during study. **Participants :** patients undergoing elective cesarean section will be included in this study . **Inclusion criteria :** Filling written informed consent form , and American society of anesthesiologist physical status I or II . **Exclusion criteria :** any absolute or relative contraindication for spinal anesthesia , core body temperature more than 37.5 or lower than 36.5 °C , BMI>25 , cardiac block or dysrhythmia, history of Psychiatric disease , history of taking α receptor antagonist drugs , history of hypertension or taking any antihypertensive drug , history of any cardiac disease (ischemic , valvular , block) , history of renal failure , hepatic failure , history of allergy to study drugs , failure or incomplete spinal block , excessive hemorrhage that need transfusion . **Intervention :** Spinal anesthesia will be done using 12.5 Mg bupivacaine and 5 microgram dexmedetomidine in study group , and 12.5 Mg bupivacaine and 0.5 ml 0.9% Normal saline in control group . Drugs will be prepared by nurse anesthesia in equal volume (3 ml) for both group . **Primary outcome :** Incidence of shivering and core body temperature changes during spinal anesthesia and in post anesthesia care unit . The neonate APGAR and assessment of cardiovascular profile are the secondary outcomes of study . The core body temperature will be measure in

tympenic membrane using termoscan , and in 5 minute intervals . Incidence of shivering will be evaluate by direct observation , and will be graded by 4 point scale . Cardiovascular profile including systolic and diastolic blood pressure and heart rate will be monitored continuously and be recorded in 5 minute intervals. Anesthesia complications such as hypotension, bradycardia , nausea and vomiting will be evaluate , record and treated if needed. Data will be analyzed by SPSS software , and using Chi-square test , Student's t-test, and ANOVA .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511301766N7**
Registration date: **2016-01-12, 1394/10/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-12, 1394/10/22

Registrant information

Name

Karim Nasseri

Name of organization / entity

Kurdistan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences ,Vice chancellor

for research

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of intrathecal dexmedetomidine effect on core body temperature and shivering during spinal anesthesia for cesarean section

Public title

Evaluation of intrathecal dexmedetomidine effect on core body temperature and shivering during spinal anesthesia for cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :Filling informed consent form of study by patients ; American society of anesthesiologist physical status I or II Exclusion criteria :any absolute or relative contraindication for spinal anesthesia ; core body temperature more than 37.5 or lower than 36.5 °C ; BMI>25 ; cardiac block or dysrhythmia ; history of Psychiatric disease ; history of taking α receptor antagonist drugs ; history of hypertension or taking any antihypertensive drug ; history of any cardiac disease (ischemic , valvular , block) ; history of renal failure ; history of hepatic failure ; history of allergy to study drugs ; failure or incomplete spinal block ; excessive hemorrhage that need transfusion

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

.

Secondary Ids

empty

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

Kurdistan University of Medical Sciences ethic committee

Street address

Pasdaran BLV

City

Sanandaj

Postal code**Approval date**

2015-08-15, 1394/05/24

Ethics committee reference number

MUK.REC.1394.141

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

Spinal Anesthesia

ICD-10 code

O29.5

ICD-10 code description

other complication of spinal and epidural anesthesia during pregnancy

Primary outcomes**1****Description**

Core body temperture

Timepoint

5 Minute

Method of measurement

with termoscan via tempanic membrane

2**Description**

shivering

Timepoint

Continuse

Method of measurement

Yes/No

Secondary outcomes**1****Description**

Grade of Shivering

Timepoint

continuse

Method of measurement

zero = no shivering, 1 = shivering in face or neck, 2 = muscular activity in more than one muscle group, but not generalized; and 3 = shivering involving the whole body

2

Description

The time from spinal anesthesia to beginning of shivering

Timepoint

continue

Method of measurement

The time interval from spinal anesthesia to beginning of shivering

Intervention groups

1

Description

Intervention : 5 microgram Dexmedetomidine will be added to 12.5 Mg bupivacaine 0.5% and 0.49 ml 0.9% normal saline (total volume 3 ML) for injection to spinal space in L3-L4 or L4-L5 level via 25G needle .

Category

Treatment - Drugs

2

Description

Control : 12.5 Mg bupivacaine 0.5% will be added to 0.5 ML 0.9% normal saline (total volume =3 ML) for injection to spinal space in L3-L4 or L4-L5 level via 25G needle .

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

operating room number2, Besat Hospital

Full name of responsible person

Dr.KarimNasseri

Street address

Keshavarz Street

City

Sanandaj

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kurdistan University of Medical Sciences .Vice chancellor for research

Full name of responsible person

Ebrahim Ghaderi

Street address

Pardis of University

City

Sanandaj

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

Yes

Title of funding source

Kurdistan University of Medical Sciences .Vice chancellor for research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Sanandaj Faculty of Medicine

Full name of responsible person

Dr.Ebrahim Ghaderi

Position

Epidemiologist , Head of research council of KUMS

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Department of Anesthesiology , Kurdistan University of Medical Sciences

Full name of responsible person

Dr. Karim Nasseri

Position

Associate Professor , Anesthesiologist

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact

Name of organization / entity

Sanandaj Faculty of Medicine

Full name of responsible person

Dr. Karim Nasseri

Position

Anesthesiologist , Member of department of
anesthesiology

Other areas of specialty/work

Street address

Besat Hospital , Keshavarz Street

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Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty