Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 trail 50 patients with American Society of Anesthesiologist physical statues 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 hole 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 tympanic 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

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Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Silences ,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 tempreture
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 bigning of shevering
Timepoint
continuse
Method of measurement
The time interval from spinal anesthesia to bigning of shevering

Intervention groups

1

Description
Intervention : 5 microgram Dexmedetomidine will be added to 12.5 Mg bupivacaine 0.5% and 0.49 mi 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 concil of KUMS
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Person responsible for scientific inquiries

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Department of Anesthesiokogy , Kurdistan University of Medicak Sciences
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Associate Professor , Anesthesiologist
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Person responsible for updating data

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Anesthesiologist , Member of department of anesthesiology

Other areas of specialty/work

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Web page address

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