Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of intrathecal dexmedetomidine effect on block characteristics during spinal anesthesia for cesarean section

Protocol summary

Summary

Objective: Evaluation of effect of intrathecal co-administration of dexmedetomidine and bupivacaine on spinal anesthesia blocks characteristics in patient undergoing elective caesarean section . Setting : In this prospective randomized double blind clinical trail 50 patients who will scheduled for cesarean section under spinal anesthesia in besat hospital of sanandaj will be randomly divided in to 2 equal 25 patient group . Inclusion criteria: writing consent form, American Society of Anesthesiologist physical status 1 or 2. Exclusion criteria: preeclampsia or eclampsia, diabetes mellitus, chronic hypertension, cardiovascular disease, renal disease, hepatic failure, and known allergy to study drugs. Method: After insertion of two G20 venous catheters in dorsum of patient’s hands 10 Ml/Kg normal saline will be infused to patients. Standard monitoring will be start for patient and basic values will be record. Spinal anesthesia will be done in sitting position via L3-L4 or L4-L5 space using disposable (G=26) needle. Following spinal anesthesia patient immediately turned to supine position and about 5 degree head down. Intervention: induction of spinal anesthesia will be done by using 12.5 mg bupivacaine plus 5 mic dexmedetomidine in study group, and the same value of bupivacaine plus 0.5 ml 0.9% normal saline in control group (volume of drug will be reached to 3 ml by adding stilled water in both group). Primary outcome: peak of sensory block and the needing time to reach that, the needing time to reach motor block to highest degree of modified bromage scale, time of regression of sensory block to level of S1 and regression of motor block to modified bromage scale 1. Secondary outcome: cardiovascular change during first 30 min of anesthesia, and complication of block. Blinding: patient, anesthesiologist who do spinal anesthesia, and the anesthesiologist who evaluate study outcomes are unaware about patients grouping .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512051766N8**
Registration date: **2016-01-20, 1394/10/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-20, 1394/10/30

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

2015-05-22, 1394/03/01

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 block characteristics during spinal anesthesia for cesarean section

Public title
Evaluation of intrathecal dexmedetomidine effect on block characteristics during spinal anesthesia for cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria : American Society of Anesthesiologist Physical status 1 or 2 Exclusion criteria : Any absolute or relative contraindication for spinal anesthesia ; BMI > 25 ; history of taking α2 antagonist drugs ; history of hypertension or antihypertensive drug taking ; history of heart disease (ischemic ,valular ,blocks) ; renal failure ; hepatic disease ; history of allergy to study drugs ; inadequate spinal block level

Age
From **18 years** old to **45 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
Pardis of medicien faculty , 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
Other comp

ICD-10 code description
O29.8

Primary outcomes

1

Description
peak of sensory block

Timepoint
every 15 min until reaching equal result inthree consecutive session

Method of measurement
using Cotton alcohol method in midclavicular line from distal to proximal of body

2

Description
needing time to reach the peak of sensory block

Timepoint
every 2 min until reaching equal result in three consecutive session

Method of measurement
using Cotton alcohol method in midclavicular line from distal to proximal of body

3

Description
needing time to reach motor block to highest degree

Timepoint
every 15 min

Method of measurement
modified bromage scale

4

Description
time of regression of sensory block

Timepoint
every 15 min in post anesthesia care unit

Method of measurement
time need to regression of sensory block to level of S1 using

5

Description
time need to regression of motor block

Timepoint

every 15 min in post anesthesia care unit

Method of measurement

based on modified bromage scale

Secondary outcomes

1

Description

cardiovascular chang

Timepoint

every 10 min

Method of measurement

Using indirect blood pressure measurement via automated devise

Intervention groups

1

Description

Intervention : 12.5 Mg bupivacaine 0.5% plus 5 mic dexmeditomidine (total volume 3 Ml by adding distilled water)

Category

Treatment - Drugs

2

Description

Control : 12.5 Mg bupivacaine 0.5% plus 0.5 Ml 0.9% normal saline (total volume 3 Ml)

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

Besat hospital , 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

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Anesthesiokogy , Kurdistan University of Medicak Sciences

Full name of responsible person

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Position

Associate Professor / Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Sanandaj Faculty of Medicine

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Position

Anesthesiologist / Department of Anesthesiology

Other areas of specialty/work

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Besat Hospital , Keshavarz Street

City

Sanandaj

Postal code

Phone

00

Fax

Email

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