Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparative study on the effect and non effect of adding Dexmedetomidine than intrathecal Marcaine than Sufentanil in elective cesarean surgery

Protocol summary

Summary

This study will be done with aim to Comparative study on the effect of adding Dexmedetomidine than intrathecal Marcaine than Sufentanil in elective cesarean surgery in Imam Reza Hospital in Kermanshah city. This study is one blinded clinical trial. The research population includes all patients undergoing cesarean surgery. 60 eligible patients will be selected in an available method and randomly assigned to two intervention groups. First, each group receives 500 cc of Ringer Infusion Syringe. Then the first intervention group will receive 5 mg / d of Dexmedetomidine and 10 mg of Hyperbaric marcaine 0/5%. The second intervention group will receive 5mg of sufentanil with 10mg of hyperbaric marcaine 0/5%. After the surgery, the pain and duration of analgesia and headaches are measured by means of the VAS tool and recorded in the checklist, and the two groups are compared with each other. Inclusion criteria: singleton, 18 to 45 years term pregnant women with a body mass of 18 to 30 with ASA class 1 candidate for cesarean section Exclusion criteria: Having any underlying disease such as cardiovascular disease (IHD cardiomyopathy), pre-eclampsia, Hypertension; neurological diseases such as migraine; Psychiatric diseases; History of allergy to local anesthesia; Emergency cesarean surgery; Cases requiring general anesthesia during surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101814333N82**
Registration date: **2017-10-25, 1396/08/03**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-10-25, 1396/08/03

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2017-12-31, 1396/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study on the effect and non effect of adding Dexmedetomidine than intrathecal Marcaine than Sufentanil in elective cesarean surgery

Public title

Comparative study on the effect of adding Dexmedetomidine than intrathecal Marcaine than

Sufentanil in elective cesarean surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: singleton, 18 to 45 years term pregnant women with a body mass of 18 to 30 with ASA class 1 candidate for cesarean section Exclusion criteria: Having any underlying disease such as cardiovascular disease (IHD cardiomyopathy), pre-eclampsia, Hypertension; neurological diseases such as migraine; Psychiatric diseases; History of allergy to local anesthesia; Emergency cesarean surgery; Cases requiring general anesthesia during surgery.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2016-07-13, 1395/04/23

Ethics committee reference number

kums.rec.1395.257

Health conditions studied

1

Description of health condition studied

wound cesarean

ICD-10 code

034

ICD-10 code description

Maternal care due to uterine scar from previous surgery

Primary outcomes

1

Description

Painless

Timepoint

At the time of 1, 2, 4, 6, 8, 10, 12, 16, 20 and 24 hours after the end of surgery

Method of measurement

Question from patient and visual observation (VAS)

2

Description

Headache

Timepoint

At the time of 1, 2, 4, 6, 8, 10, 12, 16, 20 and 24 hours after the end of surgery

Method of measurement

Question from patient and visual observation (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 5 mg / d of Dexmedetomidine and 10 mg of Hyperbaric marcaine 0.5%.

Category

Treatment - Drugs

2

Description

The second intervention group will receive 5mg of sufentanil with 10mg of hyperbaric marcaine 0.5%

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital
Full name of responsible person
Mahrokh Alikhani
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshh

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Sciences
Full name of responsible person
Koroush Hamzehee
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Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kermanshah University of Medical Sciences
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

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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