

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of Dexamethasone- Ketamine and Dexmedetomidine for prevention of postoperative nausea and vomiting during and after cesarean section under spinal anesthesia

Protocol summary

Summary

The aim of this study is compare Dexamethasone- Ketamine and Dexmedetomidine to prevent nausea and vomiting during and after cesarean section after in spinal anesthesia. This study is Double-blind and clinical trial in Taleghani Hospital in Arak. Inclusion criteria: single pregnancy; 18 to 35 years; elective cesarean section; ASA I and II .Exclusion criteria: general anesthesia; prescription drugs after delivery; body mass index more than 35; motion sickness; intrauterine growth retardation; history of anti emetic drugs in 24 hours before nausea and vomiting. Spinal anesthesia performed by anesthesiologists . Anesthesiologists divided randomly in 4 equal groups (each group 40 person). We injected 20 milliliter normal saline in first group. We injected 8 milligram of Dexamethasone in 20 ml of normal saline in second group. We injected 0/5 milligram in Ketamine in 20 milliliter normal saline in 10 minute in third group. We injected 1 micro gram per kilogram of Dexmedetomidine in 20 milliliter of normal saline in 10 minute in fourth Group. We recorded Number of nausea, vomiting after clamping the umbilical cord in 4 hours after surgery. We recorded Blood pressure, heart rate and arterial oxygen saturation every 5 minutes to exit recovery. We recorded patient satisfaction and total dose of Metoclopramide and degree of patient peace in all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091320258N10**
Registration date: **2016-11-08, 1395/08/18**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-11-08, 1395/08/18

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University Of Medical Sciences

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Dexamethasone- Ketamine and Dexmedetomidine for prevention of postoperative nausea and vomiting during and after cesarean section under spinal anesthesia

Public title

Comparison of Dexamethasone- Ketamine and

Dexmedetomidine for prevention of postoperative nausea and vomiting during and after cesarean section under spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: single pregnancy; 18 -35 years; elective cesarean section; ASA I,II Exclusion criteria: general anesthesia; prescription drugs after delivery; body mass index more than 35; motion sickness; Intrauterine growth retardation; history of anti-nausea and vomiting 24 hours before surgery; history of gastrointestinal disease; history of allergy; Nausea and vomiting before clamping the umbilical cord; lack of patient satisfaction.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research, Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City

Arak

Postal code

848179641

Approval date

2016-08-08, 1395/05/18

Ethics committee reference number

IR.ARAKMU.REC.1395.181

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes

1

Description

Nausa and vomitting

Timepoint

After clamping the umbilical cord

Method of measurement

Visual Analogue Scale

2

Description

Blood pressure

Timepoint

Every 5 minute to recovery

Method of measurement

Millimeter Hg

3

Description

Heart rate

Timepoint

Every 5 minute to recovery

Method of measurement

Count

4

Description

Oxygen saturation

Timepoint

Every 5 minute to recovery

Method of measurement

Percent

5

Description

Patient satisfaction

Timepoint

After recovery

Method of measurement

Visual Analogue Scale

6

Description

Total of dose of Metoclopramide

Timepoint

After recovery
Method of measurement
Miligeram

7

Description

Degree of patient peace

Timepoint

Before prescribe to after recovery

Method of measurement

Ramsay Scale

Secondary outcomes

empty

Intervention groups

1

Description

We injected 20 milliliter normal saline in first group

Category

Treatment - Drugs

2

Description

We injected 8 milligram of Dexamethasone in 20 ml of normal saline in second group.

Category

Treatment - Drugs

3

Description

We injected 0/5 milligram in Ketamine in 20 milliliter normal saline in 10 minute in third group.

Category

Treatment - Drugs

4

Description

We injected 1 microgram per kilogeram of Dexmedetomidine in 20 milliliter of normal saline in 10 minute in fourth group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Hesamodin Modir

Street address

Taleghani hospital, Emam Khomeini street, Arak

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Science

Full name of responsible person

Dr Mohammad Rafiee

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

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, Arak University of Medical Science

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

Medicine department

Full name of responsible person

Nilufar Shams

Position

Student of medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Dr Hesamodin Modir

Position

Anesthesiologist

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

Valiasr hospital, Valiasr square, Shahid Shirodi street,
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Full name of responsible person

Nilufar Shams

Position

Student of medicine

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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