

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3222 2003

###### Email address

f.farokhi@arakmu.ac.ir

##### 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**

**Street address**

Payambar Azam complex, Basij square , Sardasht, Arak

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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

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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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*