

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A comparative study on effect of low dose ketamine versus dexamethasone on intraoperative nausea and vomiting during cesarean section under spinal anesthesia

Protocol summary

Study aim

comparative study on effect of low dose ketamine versus dexamethasone on intraoperative nausea and vomiting during cesarean section under spinal anesthesia

Design

In this interventional study, 135 pregnant women who are candidates for natural childbirth will be selected and divided into three groups using block randomization method (n=45 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen.

Settings and conduct

This study will be conducted in the form of double blind in Alavi Hospital of Ardebil, Iran. Participants and clinical caregivers will not be aware of the type of medication. The variables in patients under cesarean section with spinal anesthesia with marcain 0.5% will be compared within 24 hours of operation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnancy between 35 to 40 weeks, indication for cesarean section. Exclusion criteria: Preeclampsia, eclampsia.

Intervention groups

First intervention group: Intravenous ketamine 4 mg / kg (Rotex Co, Germany), diluted in 5 ml of normal saline (Samen Co, Iran). Second intervention group: Intravenous dexamethasone 8 mg (Iran daroo Co, Iran), diluted in 5 ml of normal saline (Samen Co, Iran). Control group: Intravenous normal saline 5 ml (Samen Co, Iran).

Main outcome variables

Nausea, Vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150808023559N18**

Registration date: **2018-04-11, 1397/01/22**

Registration timing: **prospective**

Last update: **2018-04-11, 1397/01/22**

Update count: **0**

Registration date

2018-04-11, 1397/01/22

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3373 3011

Email address

s.matin@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on effect of low dose ketamine versus dexamethasone on intraoperative nausea and

vomiting during cesarean section under spinal anesthesia

Public title

Comparison of the effect of low-dose Ketamine and dexamethasone on the control of nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy between 35 to 40 weeks Indication for cesarean section

Exclusion criteria:

Preeclampsia Eclampsia

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned randomly by blocking in one of the three specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of three methods will be selected.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and clinical caregivers are not aware of the type of medication.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City

Ardabil

Province

Ardabil

Postal code

5615783134

Approval date

2018-01-30, 1396/11/10

Ethics committee reference number

lr.arums.rec.1396.230

Health conditions studied

1

Description of health condition studied

Cesarean section

ICD-10 code

O82.9

ICD-10 code description

Delivery by caesarean section

Primary outcomes

1

Description

Nausea

Timepoint

Within 24 hours of operation

Method of measurement

Through a score of N & V.

2

Description

Vomiting

Timepoint

Within 24 hours of operation

Method of measurement

Through a score of N & V.

Secondary outcomes

1

Description

Dizziness

Timepoint

Within 24 hours of operation

Method of measurement

question of patient

Intervention groups

1

Description

Intervention group: Intravenous ketamine 4 mg / kg (Rotex Co, Germany), diluted in 5 ml of normal saline (Samen Co, Iran).

Category

Treatment - Drugs

2

Description

Intervention group: Intravenous dexamethasone 8 mg (Iran daroo Co, Iran), diluted in 5 ml of normal saline (Samen Co, Iran).

Category

Treatment - Drugs

3

Description

Control group: Intravenous normal saline 5 ml (Samen Co, Iran).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Sona Emami

Street address

Alavi Hospital, Moadi street, Ardabil

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Sona Emami

Position

Anesthesiology Asisstant

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Associate professor

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Specialist

Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

Anesthesiology

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Ardabil

Postal code**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available