Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim
comparative study on effect of low dose ketamine versus dexamethasone on intraoperative nausea and vomitting 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=45in 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 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

vomitting 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
Ir.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
City
Ardabil
Province
Ardabil
Postal code
5615783134
Phone
+98 45 3342 8888
Email
sona_emami@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Masoud Entezari
Street address
Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran
City
Aedabil
Province
Ardabil
Postal code
5615783134
Phone
+98 45 3352 2247
Email
m.entezari@arums.ac.ir
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
Street address
Alavi Hospital, Moadi street, Ardabil
City
Ardabil
Province
Ardabil
Postal code
5615783134
Phone
+98 45 4233 8888
Email
sona_emami@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Ahmad Gazi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Alavi Hospital, Moadi street, Ardabil
City
Ardabil

Province
Ardabil
Postal code
5615783134
Phone
+98 45 4233 8888
Email
dr.ghaziahmad@gmail.com

Person responsible for updating data

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
Street address
Alavi Hospital, Moadi street, Ardabil
City
Ardabil
Province
Ardabil
Postal code
5615783134
Phone
+98 45 4233 8888
Email
sona_emami@yahoo.com

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