Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The Effect of Low-Dose Intravenous Ketamine on prevention of post dural puncture headache in patients undergoing Cesarean delivery by spinal anesthesia

Protocol summary

Study aim

Determining the effect of low dose venous ketamine on prevention of headache after spinal anesthesia in patients undergoing elective cesarean section

Design

This is a double-blind non-randomized clinical trial study in which 70 patients undergoing elective cesarean section with spinal anesthesia are studied.

Settings and conduct

The place of the study is the operation room and gynecology department of Vali-e-Asr Hospital in Birjand. Patients are unaware of the type of prescripted medication. Medications are provided in uniform syringes encoded by one of the operating room nurses who are not included in the study. After doing spinal anesthesia and approximately 5 Minutes before the start of the procedure, the patients in the case group received 0.15 mg / kg body weight of ketamine administered intravenously, and in the control group, normal saline are used as placebo. In both groups, the incidence of headache, itching and nausea and severity at 1, 4, 12, and 24 hours after surgery are measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent, grades ASA 1-2, no history of migraine or other types of headaches, psychological problems, coagulation disorders and addiction. In case of unwanted complications like allergic reactions, respiratory complications, severe bleeding, bronchospasm, change in type of anesthesia, and more than one attempt to produce spinal anesthesia, the patient is excluded from the study.

Intervention groups

Intervention group: receiving intravenous ketamine
Control group: receiving normal saline

Main outcome variables

Headache, nausea and itching

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190202042589N1**
Registration date: **2019-02-14, 1397/11/25**
Registration timing: **prospective**

Last update: **2019-02-14, 1397/11/25**
Update count: **0**

Registration date

2019-02-14, 1397/11/25

Registrant information

Name

Ali Nademi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3276 3132

Email address

ali.nademi@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-04-20, 1398/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of Low-Dose Intravenous Ketamine on prevention of post dural puncture headache in patients undergoing Cesarean delivery by spinal anesthesia

Public title
The Effect of Low-Dose Intravenous Ketamine on prevention of post dural puncture headache

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Informed Consent to Participate in this Plan ASA class 1-2 Patients undergoing Cesarean delivery Spinal anesthesia
Exclusion criteria:
history of Coagulation disorders history of Mental Disorders and Seizure history of Drug addiction history of migraine or other types of headaches Emergency situation of mother and fetus Cesarean delivery during General Anesthesia

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are not aware of the type of prescribed medications which are in uniform syringes encoded by one of the operating room nurses who are not in the study. The investigator is not informed about the groups until the end of the data collection.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Birjand University of Medical Sciences
Street address
Birjand University of Medical Sciences ,Ghaffari St.,
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷

Approval date
2019-02-02, 1397/11/13

Ethics committee reference number
ir.bums.REC.1397.330

Health conditions studied

1

Description of health condition studied
Headache after spinal anesthesia due to dural puncture

ICD-10 code
O74.5

ICD-10 code description
Spinal and epidural anesthesia-induced headache during labor and delivery

Primary outcomes

1

Description
Headache

Timepoint
The incidence of headache and its severity is measured at 1, 4, 12, and 24 hours after surgery.

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Nausea

Timepoint
The incidence of nausea and its severity is measured at 1, 4, 12, and 24 hours after surgery

Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group: About 5 minutes before surgery, patients in the intervention group receive 0.15 mg / kg body weight of ketamine (manufactured by STEROP Belgium) by intravenous injection.

Category

Prevention

2

Description
Control group: In the control group, normal saline is used as a placebo.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital in Birjand
Full name of responsible person
Malihe Zangooei
Street address
Vali-e-Asr hospital , Ghafari St
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3244 3000
Email
alindm97@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Tooba Kazemi
Street address
Ghaffari St., Birjand University of Medical Sciences, Deputy of Research and Technology
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1200
Email
research@bums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Ali Nademi
Position
student
Latest degree
Bachelor
Other areas of specialty/work
General Practitioner
Street address
Ghaffari St., Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
9783116641
Phone
+98 56 3276 3132
Email
alindm97@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Malihe Zangooie
Position
assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ghaffari St., Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
۹۷۱۷۸۵۳۵۷۷
Phone
+98 56 3238 1501
Email

mzangoue@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Birjand University of Medical Sciences

Full name of responsible person
Ali Nademi

Position
student

Latest degree
Bachelor

Other areas of specialty/work
General Practitioner

Street address
Ghaffari St., Birjand University of Medical Sciences

City
Birjand

Province
South Khorasan

Postal code
9783116641

Phone
+98 56 3276 3132

Email
alindm97@gmail.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