Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study of the effect of Granisetron in the prevention of blood pressure drops after spinal anesthesia for cesarean delivery

Protocol summary

Study aim
Study of the effect of granisetron in the prevention of blood pressure drop after spinal anesthesia in cesarean delivery

Design
This study is one-blinded clinical trial.The research population will be included all female candidates for cesarean delivery refer to Imam Reza and Motazedi hospital of Kermanshah.106 eligible patients will be selected conveniently and randomly will be assigned to intervention and control groups.

Settings and conduct
This study which will be conducted in Imam Reza and Motazedi hospital of Kermanshah city is one-blinded one, that participants are unaware of group allocation.Patients will be monitored at the beginning of enterance to the operating room by BP, Spo2, ECG and HR.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Pregnant women aged 15-45; ASA Class 1 who are candidate for elective cesarean delivery under spinal anesthesia Exclusion criteria:Neurological disorders; Spinal abnormalities;; Liver disease;BMI>30

Intervention groups
In intervention group, patients will receive 2 mg of Granisetron 5 minutes before the spinal anesthesia via angiocontose. Then, spinal anesthesia with 15 mg of Bupivacaine will be done with a Spinal 25G needle. In control group In the control group, patients will receive 2 ml of normal saline 5 minutes before the spinal anesthesia via angiocetate. Then, spinal anesthesia with 15 mg of bupivacaine will be done with a spinal 25G needle.

Main outcome variables
Blood pressure drop

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N122**
Registration date: **2019-05-25, 1398/03/04**
Registration timing: **prospective**

Last update: **2019-05-25, 1398/03/04**
Update count: **0**

Registration date
2019-05-25, 1398/03/04

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 83 1821 4653
Email address
fforoughi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-10, 1398/03/20

Expected recruitment end date
2019-11-11, 1398/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of Granisetron in the prevention of blood pressure drops after spinal anesthesia for cesarean

delivery

Public title
Effect of Granisetron on blood pressure drops in cesarean delivery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women aged 15-45 ASA Class 1 who are candidate for elective cesarean delivery under spinal anesthesia
Exclusion criteria:
Neurological disorders Spinal abnormalities Liver disease BMI>30
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **106**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomly Individually by random number table via code receipt
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the participants will be kept blinded to the allocation of study groups, dosage of drug and the drug manufacturer. In this way that participants will be unaware of how the participants will be coded and how much the groups will receive
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2019-05-08, 1398/02/18
Ethics committee reference number
ir.kums.rec.1398.142

Health conditions studied

1

Description of health condition studied
Maternal hypotension
ICD-10 code
O26.5
ICD-10 code description
Maternal hypotension syndrome

Primary outcomes

1

Description
Blood pressure drop
Timepoint
Every 3 minutes to 30 minutes, and then every 10 minutes until the end of the surgery
Method of measurement
Using Holter Monitoring

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group, patients will receive 2 mg of Granisetron 5 minutes before the spinal anesthesia via angiocontose. Then, spinal anesthesia with 15 mg of Bupivacaine will be done with a Spinal 25G needle.
Category
Treatment - Drugs

2

Description
In the control group, patients will receive 2 ml of normal saline 5 minutes before the spinal anesthesia via angiocetate. Then, spinal anesthesia with 15 mg of bupivacaine will be done with a spinal 25G needle.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Seyedeh Nastaran Tavakoli Lahijani
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
nassitl@gmail.com

2

Recruitment center
Name of recruitment center
Motazedi Hospital
Full name of responsible person
Seyedeh Nastaran Tavakoli Lahijani
Street address
Ferdowsi Square
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3424 6351
Email
nassitl@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3836 0014
Email
fnajafi@kums.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Seyedeh Nastaran Tavakoli Lahijani
Position
Resident of Anesthesia
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
nassitl@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Parisa Golfam
Position
Member of the faculty of Kermanshah University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Emam Reza Hospital, Parastar Boulevard

City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
pgolfam@kums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Seyedeh Nastaran Tavakoli Lahijani
Position
Resident of Anesthesia
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
Street address
Emam Reza Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
nassitl@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
Informed Consent Form
Yes - There is 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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared.
When the data will become available and for how long
3 months
To whom data/document is available
If requested, results will be made available to other academic researchers
Under which criteria data/document could be used
Collected data is confidential and will not be shared with anyone else
From where data/document is obtainable
To receive the documentation, email send for update manager
What processes are involved for a request to access data/document
In a 15-day period, the documents will be sent e-mail
Comments