

# 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 entrance 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 angiocatheter. 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 angiocatheter. 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 angiocatose. 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 angiocatose. 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**