

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

study the effectiveness of ondansetron on the prevention of hypotension after spinal anesthesia

Protocol summary

Study aim

Study of the effectiveness of ondansetron on the prevention of hypotension after spinal anesthesia

Design

This is an open label clinical trial. All pregnant women who are candidates for the cesarean delivery and spinal anesthesia referring to Imam Reza hospital in Kermanshah city will be enrolled in the study. 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 hospital of Kermanshah city is open label. At the beginning of the study, some symptoms, such as blood pressure, nausea, headache, and chills, will be recorded on a checklist. After the end of the study, the symptoms will be re-evaluated and two groups will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women aged 18 -37 years; Female candidates for cesarean delivery and spinal anesthesia
Exclusion criteria: Neurological disorders; Injection site infection; Liver Disease and BMI > 30

Intervention groups

The intervention group will receive 7 ml/kg of ondansetron intravenously before the start of spinal. The control group will receive 7 ml/kg of normal saline intravenously before the start of spinal.

Main outcome variables

blood pressure; nausea and vomiting; Headache; Chill

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N99**

Registration date: **2018-08-18, 1397/05/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-18, 1397/05/27**

Update count: **0**

Registration date

2018-08-18, 1397/05/27

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

2018-08-16, 1397/05/25

Expected recruitment end date

2018-10-17, 1397/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

study the effectiveness of ondansetron on the prevention of hypotension after spinal anesthesia

Public title

study of the effectiveness of ondansetron on the prevention of hypotension after spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged between 18 -37 years Female candidates for cesarean delivery and spinal anesthesia

Exclusion criteria:

Neurological disorders Injection site infection Liver Disease and BMI> 30

Age

From **18 years** old to **37 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Individually randomization by random number table via code receipt

Blinding (investigator's opinion)

Not blinded

Blinding description**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

2017-12-13, 1396/09/22

Ethics committee reference number

ir.kums.rec.1396.507

Health conditions studied**1****Description of health condition studied**

Spinal anesthesia

ICD-10 code

O29.5

ICD-10 code description

Other complications of spinal and epidural anesthesia during pregnancy

Primary outcomes**1****Description**

blood pressure

Timepoint

Immediately after Spinal, every 3 minutes to 30 minutes

Method of measurement

Using the barometer device

2**Description**

Nausea and vomiting

Timepoint

The beginning and the end of the study

Method of measurement

Asking of patient

3**Description**

Headache

Timepoint

The beginning and the end of the study

Method of measurement

Ask the patient

4**Description**

Chill

Timepoint

The beginning and the end of the study

Method of measurement

Asking of patient

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group will receive 7 ml/kg of ondansetron intravenously before the start of spinal.

Category

Treatment - Drugs

2

Description

The control group will receive 7 ml/kg of normal saline intravenously before the start of spinal.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Mahin Molaei

Street address

Parastar Blvd, Emam Reza Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6309

Email

arshiyamolaie58@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

Mahin Molaei

Position

Resident of Anesthesia

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Parastar Blvd, Emam Reza Hospital

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Kermanshah

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6715847141

Phone

+98 83 3427 6309

Email

arshiyamolaie58@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

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Parastar Blvd, Emam Reza Hospital

City

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Email

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Mahin Molaei

Position

Resident of Anesthesia

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

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

4 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