Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 a open label clinical trial. All pregnant women who are candidates for the cesarean delivery and spinal anesthesia referreing 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)
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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
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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
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+98 83 3836 0014
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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
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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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
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Person responsible for updating data

Contact

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Full name of responsible person
Mahin Molaei

Position
Resident of Anesthesia

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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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