Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

prophylactic effects of ondansetron with dexamethasone and metoclopramide with dexamethasone on spinal anesthesia complications in caesarean section; a double blind clinical trial study

Protocol summary

Study aim
In this study we intend to investigate the effect of two different drugs on the overall spinal complications.

Design
A clinical trial with a control group with parallel-bilateral blind groups is available on 120 patients.

Settings and conduct
The present study is a double-blind randomized clinical trial on patients scheduled for surgery under spinal anesthesia after obtaining approval from the ethics committee of Khalkhal University of Medical Sciences and explaining the procedure and obtaining written permission from the patient.

Participants/Inclusion and exclusion criteria
Cesarean section patient

Intervention groups
The study samples were randomly divided into three groups: a) patients receiving prodrugs ondansetron (4 mg) and dexamethasone (4 mg), b) patients receiving dexamethasone (4 mg) and metoclopamide (5 mg) as prophylaxis, and Group c) Patients who received 5 cc of normal saline and are in the control group. Five minutes before the start of the spinal, the first group will be injected with 4 mg of ondansetron 4 mg of intravenous dexamethasone, the second group with 4 mg of dexamethasone and 5 mg of intravenous metoclopramide, and the third group with 3 cc of normal saline. L3-L4 and L4-L5 lumbar intervertebral space are anesthetized using Quick Spinal Needle No. 25 and Bupivacaine 0.5%

Main outcome variables
Reduce nausea and vomiting,reduce shivering, reduce blood pressure, reduce headaches

General information

Reason for update

Acronym
PODMDSCC

IRCT registration information
IRCT registration number: **IRCT20210403050823N1**
Registration date: **2021-04-12, 1400/01/23**
Registration timing: **prospective**

Last update: **2021-04-12, 1400/01/23**
Update count: **0**

Registration date
2021-04-12, 1400/01/23

Registrant information

Name
solmaz saeidi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-13, 1400/01/24

Expected recruitment end date
2021-07-15, 1400/04/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

prophylactic effects of ondansetron with dexamethasone and metoclopramide with dexamethasone on spinal anesthesia complications in caesarean section; a double blind clinical trial study

Public title
prophylactic effects of ondansetron with dexamethasone and metoclopramide with dexamethasone on spinal anesthesia complications in caesarean section; a double blind clinical trial study
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ASA I-ASAII Age between 18-45
Exclusion criteria:
Past medical history Drug history Dissatisfaction Emergency cesarean
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
For control patients, the same amount of drug is injected as a drain, the injector does not know the contents of the syringe.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Khalkhal School of Medical Sciences
Street address
Mozaffar
City
Khalkhal
Province
Ardabil
Postal code
5681761351
Approval date
2021-02-28, 1399/12/10
Ethics committee reference number
IR.KHALUMS.REC.1399.020

Health conditions studied

1

Description of health condition studied
Cesarean section
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hypotension
Timepoint
18 Month
Method of measurement
Sphygmomanometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the first intervention group, 5 mg of ondansetron, 4 mg of intravenous dexamethasone, and in the second group, 4 mg of dexamethasone and 5 mg of metoclopramide intravenously will be injected from the same drug company, five minutes before the start of the spinal, in the second group. The L3-L4 and L4-L5 lumbar vertebrae are subjected to spinal anesthesia by an anesthesiologist with a single puncture of the dorsum using a Quick Spinal Needle No. 25 and 0.5% bupivacaine, and are immediately returned to the supine position.
Category
Treatment - Drugs

2

Description
Control group: In the control group, Equal volume of normal saline, will be injected from the same drug company, five minutes before the start of the spinal, The L3-L4 and L4-L5 lumbar vertebrae are subjected to spinal anesthesia by an anesthesiologist with a single puncture of the dorsum using a Quick Spinal Needle No. 25 and 0.5% bupivacaine, and are immediately returned to the supine position.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Family Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khalkhal University of Medical Sciences
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Esmaeil Mehrayin
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Khalkhal 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
Khalkhal University of Medical Sciences
Full name of responsible person
Solmaz Saeidi
Position
Instructor
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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