

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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 metoclopramide (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

Country

Iran (Islamic Republic of)

Phone

+98 45 3242 6606

Email address

solmaz.saeidi@gmail.com

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-ASAI 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

Type of organization providing the funding
Academic

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
Full name of responsible person
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

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