

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of the ondansetron 4 mg in combination with dexamethasone 4 mg and dexamethasone 8 mg on post operative nausea and vomiting after elective cesarean section under spinal anesthesia

Protocol summary

Study aim

Determination the effect of low dose of dexamethasone on prevention of nausea and vomiting after cesarean section

Design

A randomized, double-blind, placebo controlled clinical trial. 135 Patients will randomly allocated to 3 groups using balanced block randomization. The study is phase 3

Settings and conduct

The site of research is Yas Hospital. After approval by the Ethics and Clinical Studies Committee of Tehran University of Medical Science the investigation will be started. Informed consents will be obtained from all of the patients. The study drugs are being prepared by a person who is not subsequently involved in the research and will be packed in an envelope that the patient code has been written on it and just before spinal anesthesia will be opened and injected. The anesthesiologist of operation room and all operation and recovery room nurses and the nurses responsible for the questionnaire are unaware of the type of drug and the patient group. Incidence of nausea and vomiting will evaluate intraoperatively, in the recovery room and 3, 6, 12, 24 hrs postoperatively.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female 18-45 yrs, ASA class 1-2, uncomplicated pregnancy, elective cesarean section
Exclusion criteria: History of motion sickness and severe morning sickness, symptoms of cardiovascular, hepatic, renal and psychotic diseases, unwillingness to work with scholars

Intervention groups

Just before spinal anesthesia group 1: 4 mg ondansetron plus 4 mg dexamethasone with 3 cc volume, group 2: 4 mg ondansetron plus 8 mg dexamethasone with 3 cc volume and group 3: 4 mg ondansetron and normal saline with 3 cc volume will receive intravenously.

Main outcome variables

Incidence of nausea and vomiting after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190409043219N2**

Registration date: **2019-09-28, 1398/07/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-28, 1398/07/06**

Update count: **0**

Registration date

2019-09-28, 1398/07/06

Registrant information

Name

Saghar Samimi Sadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4216 0000

Email address

sagharsamimi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of the ondansetron 4 mg in combination with dexamethasone 4 mg and dexamethasone 8 mg on post operative nausea and vomiting after elective cesarean section under spinal anesthesia

Public title

Determination the effect of low dose of dexamethasone on prevention of post operative nausea and vomiting after elective cesarean section

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Female 18-45 yrs ASA class 1-2 Uncomplicated pregnancy Elective cesarean section

Exclusion criteria:

history of motion sickness and severe morning sickness symptoms of cardiovascular ,hepatic,renal and psychotic disease Refuse to cooperate with researchers

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will randomly allocated to 3 treatment groups using balanced block randomization. There are 3 interventions therefore the blocks will contain 6 letters(AABBCC) and we will have 22 blocks in total ($135/6=22$). We can have twenty block models that they will be arranged in random order and finally the 2 next blocks will select randomly among that 20 models and will be added.

Blinding (investigator's opinion)

Double blinded

Blinding description

The study medications are prepared by an anesthesiologist who does not otherwise participated in the study and then are enveloped and sealed and patient's code are recorded on it. The envelopes will open in operation room just before spinal anesthesia by an anesthesiologist who is blinded to patient's study group and type of solution and then will inject intravenously. All of the nurses and patients are blinded to the type of solution and to the patient's study group

allocation.also the nurse who fill the questionnaire

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics and Clinical Studies Committee of Tehran University of Medical Sciences

Street address

Yas Hospital,North Ostad Nejatollahi Ave, Karim Khan Zand St.

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2017-09-11, 1396/06/20

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.3700

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

post operative nausea and vomiting

ICD-10 code

R68.8

ICD-10 code description

Other general symptoms and signs

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

Incidence of nausea and vomiting after cesarean section

Timepoint

Intraoperatively, in the recovery room and 3,6,12,24 hrs postoperatively

Method of measurement

The frequency of nausea and vomiting will be recorded on a questionnaire

Secondary outcomes

1

Description

severity of postoperative nausea

Timepoint

intraoperatively, in recovery room and 3,6,12,24 hrs postoperatively

Method of measurement

the severity of nausea will be recorded on a questionnaire

Intervention groups

1

Description

4 mg ondansetron plus 4 mg dexamethasone just before spinal anesthesia intravenously.

Category

Prevention

2

Description

Intervention group: 4 mg ondansetron plus 8mg dexamethasone just before spinal anesthesia intravenously.

Category

Prevention

3

Description

Control group: 4 mg ondansetron increased to 3 cc by adding normal saline just before spinal anesthesia intravenously

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Saghar Samimi Sadeh

Street address

Yas Hospital, North Ostad Nejatollahi Ave, Karim Khan Zand Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

DR. mohammad ali sahraeeian

Street address

6th floor, Tehran University of Medical Sciences
central organization, corner of Qods street, Keshavarz
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Saghar Samimi Sadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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