Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of the ondansetrone 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 ondansetrone 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 boulevard
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Tehran
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Tehran
Postal code
1417653761
Phone
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Fax
Email
vcr@tums.ac.ir
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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Yas hospital,North Ostad nejatollahi Ave,Karim Khan Zand Street
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Person responsible for updating data

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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