

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparison of the effect of combination of Metoclopramide and Dexamethasone with Ondrosterone and Midazolam in the prevention of nausea and vomiting during and after cesarean section patients with spinal anesthesia

Protocol summary

Study aim

Determining the effect of metoclopramide combination of dexamethasone with endosterone and midazolam on the prevention of recurrence and exfoliation during and after cesarean section in patients with spinal anesthesia

Design

150 patients with cesarean section will be selected. Clinical trials will be without control groups with parallel groups. Accidentalization and blindness have not been observed in the study. The study will be conducted in phase 3 of the clinical trial.

Settings and conduct

The study will be held at Alavi Hospital in Ardabil. The study will be conducted in phase 3. Blindness has not been observed in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: cesarean section indication Exclusion criteria: Having any chronic disease, Drug addiction

Intervention groups

Intervention group1: This group includes 75 pregnant women with cesarean section indications. In this group, metoclopramide ampoules will be injected into patients in 10 mg intravenously and dexamethasone 8 mg intravenously. Intervention group2: This group includes 75 pregnant women with cesarean section indications. To this group, patients will be injected with Andansteron ampoules 4 mg intravenously and Midazolam 10 mg intravenously.

Main outcome variables

Vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190901044658N2**

Registration date: **2020-06-22, 1399/04/02**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-22, 1399/04/02**

Update count: **0**

Registration date

2020-06-22, 1399/04/02

Registrant information

Name

Shahla Farzipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 0739

Email address

m.rezayi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of combination of Metoclopramide and Dexamethasone with Ondrosterone

and Midazolam in the prevention of nausea and vomiting during and after cesarean section patients with spinal anesthesia

Public title

Comparison of the effect of metoclopramide and dexamethasone with androsterone and midazolam in the prevention of nausea and vomiting during and after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having a cesarean surgery indication

Exclusion criteria:

Having Chronic disease Drug addiction

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

No. 1, Daneshgah Ave

City

Ardabil

Province

Ardabil

Postal code

5613843793

Approval date

2020-01-18, 1398/10/28

Ethics committee reference number

IR.ARUMS.REC.1398.577

Health conditions studied

1

Description of health condition studied

Caesarean section

ICD-10 code

O80

ICD-10 code description

Encounter for full-term uncomplicated delivery

Primary outcomes

1

Description

Vomiting

Timepoint

Before cesarean section and after cesarean section

Method of measurement

Number of patients vomit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: This group includes 75 pregnant women with cesarean section indications. To this group, metoclopramide ampoules will be injected into patients 10 mg intravenously by Osweh and dexamethasone 8 mg intravenously by Caspian Company under anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group2: This group includes 75 pregnant women with cesarean section indications. To this group, Andansteron ampoules will be injected into patients 4 mg intravenously by Elixir Daru and Midazolam 10 mg intravenously by Abu Reihan Company under anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi hospital

Full name of responsible person

Dr Parvin Jabbari

Street address

No. 1, Moallem Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Parvaneh Naftchi
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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
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Shahla Farzipour
Position
Associate professor
Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The questionnaires will be made available anonymously and with a file number

When the data will become available and for how long

After completing the study

To whom data/document is available

University professors

Under which criteria data/document could be used

In order to find out how to work in SPSS file, anonymous questionnaires will only be available with file number.

From where data/document is obtainable

Contact Dr. Shahla parzipour

What processes are involved for a request to access data/document

Information is available after contacting Dr. Shahla farzipour and University approval

Comments