Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Investigating the effect of intraperitoneal injection of ondansetron during elective caesarean section on postoperative pain intensity in pregnant mothers undergoing the first repeated caesarean section In kamali hospital: A clinical trial study

Protocol summary

Study aim
Determining the effect of intraperitoneal injection of ondansetron during surgery on reducing pain after cesarean section

Design
Two arm parallel group randomised trial with 30 pregnant women in each group, randomized with computer-generated table of random numbers.

Settings and conduct
This study will be conducted in Kamali Hospital on pregnant women candidates for caesarean section. Patients who have signed informed consent to participate in the project will be randomly assigned to two groups.in the first group Ondansetron 8 mg ampoule with 12 cc of normal saline is poured into the abdominal cavity before closing the peritoneum. , and in the second group 20cc of normal saline is poured into the abdominal cavity before closing the peritoneum. Then (0, 0.5, 1, 1.5, 3, 6) hours after the surgery, the pain scre is determined using a visual scale and compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: candidate for cesarean delivery due to a previous cesarean section Having a history of cesarean delivery healthy fetus ASA II Age between 20-40 years gestational age of term. Exclusion criteria: Having an underlying disease, Emergency cesarean section, History of ondansetron allergy, Receiving painkillers or sedatives 24 hours before surgery.

Intervention groups
Control group: 20cc of normal saline is poured intraperitoneally into the abdominal cavity before closing the peritoneum. Intervention group: Ondansetron 8 mg ampoule with 16 cc of normal saline is poured intraperitoneally into the abdominal cavity before closing the peritoneum.

Main outcome variables
The pain score after cesarean delivery

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220610055121N1**
Registration date: **2022-09-12, 1401/06/21**
Registration timing: **prospective**

Last update: **2022-09-12, 1401/06/21**
Update count: **0**

Registration date
2022-09-12, 1401/06/21

Registrant information
Name
Ferdos Zamani Khalili
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 26 3253 9067
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-10-22, 1401/07/30
Expected recruitment end date
2022-11-22, 1401/09/01
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of intraperitoneal injection of ondansetron during elective caesarean section on postoperative pain intensity in pregnant mothers undergoing the first repeated caesarean section In kamali hospital: A clinical trial study

Public title

Evaluating the effect of intraperitoneal injection of ondansetron during elective caesarean section on postoperative pain intensity after caesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A candidate for cesarean delivery due to a previous cesarean section Having a history of cesarean delivery healthy fetus ASA II Age between 20-40 years gestational age of term

Exclusion criteria:

Having an underlying disease Emergency cesarean section History of ondansetron allergy Receiving painkillers or sedatives 24 hours before surgery

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Group assignment is determined from a computer-generated table of random numbers.Some opaque envelopes are used for concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Completion of the final information is up to the person who is unaware of the type of treatment and also the patients and the specialist will be blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Alborz University of Medical Sciences (Research Ethics Committee)

Street address

Taleghani Square, North Taleghani Boulevard, Administrative Town, Alborz University of Medical Sciences

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2022-08-13, 1401/05/22

Ethics committee reference number

IR.ABZUMS.REC.1401.122

Health conditions studied

1

Description of health condition studied

Examining the pain level of pregnant mothers after cesarean section

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain score

Timepoint

0, 0.5, 1, 1.5, 3, 6 hours after the surgery

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Ondansetron 8 mg ampoule (Exir,Iran) with 16 cc of normal saline (Total 20 cc) is poured intraperitoneally into the abdominal cavity before closing the peritoneum.

Category

Treatment - Drugs

2

Description
Control group: 20cc of normal saline is poured intraperitoneally into the abdominal cavity before closing the peritoneum.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali Hospital
Full name of responsible person
Ferdos Zamani Khalili
Street address
Shahid Beheshti St., Shohada Square, Kamali St.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Hatem Godini
Street address
Karaj-Golshahr-Safarian Street-Department of Research and Technology of Alborz University of Medical Sciences
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research@abzums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Ferdos Zamani Khalili
Position
General medicine student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Position

General medicine student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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