Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of combined Paracetamol(Apotel) and Dexamethasone versus Paracetamol(Apotel) on post operative nausea vomiting after cesarean section

Protocol summary

Study aim

Effect of combined Paracetamol(Apotel) and Dexamethasone versus Paracetamol(Apotel) on post operative nausea vomiting after cesarean section

Design

Clinical trial with 2 parallel groups, double blind, randomised, phase 3 on 100 patients, in block randomization method with the size of 4 and 6, Random sequence will be generated by running an online program in sealed envelope website (https://www.sealedenvelope.com/).

Settings and conduct

This is a double blind clinical trial study with 100 patients referred to Taleghani hospital.They will be devided into 2 groups (Apotel and combined Apotel-Dexamethasone)randomly.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-45 years Having informed consent Having ASA I and II (American Society of Anesthesiologists) Nulliparous Singleton pregnancy Patients with elective cesarean Patients with spinal anesthesia Patients with Pfannenstiel incision in surgery. Non-inclusion criteria: Underlying disease (i.e renal, liver, cardiac and pulmonary disease) History of allergy to the drugs of study Addiction or long term using of opiate Coagulopathy or use of anticoagulant drugs Disability for pain scoring Suffering from preeclampsia or HELLP (hemolysis,elevated liver enzymes,low platelet count) or eclampsia or hepatitis Urgency cesarean section

Intervention groups

In first group 2 cc of distilled water and in second group 8 mg of Dexamethasone 30 minutes before spinal anesthesia and in both goups 1 gr of Apotel immediately after spinal anesthesia will be intravenously injected to the patients.

Main outcome variables

Vomitting score and happening of nauseae after cesarean section till 24 hours

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049175N6**
Registration date: **2021-03-02, 1399/12/12**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-02, 1399/12/12**
Update count: **0**

Registration date

2021-03-02, 1399/12/12

Registrant information

Name

Shamim Valibak

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3502

Email address

sh.valibak@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of combined Paracetamol(Apotel) and Dexamethasone versus Paracetamol(Apotel) on post operative nausea vomiting after cesarean section

Public title
Evaluation of anti analgesic and anti inflammatory drugs effect on decreasing of post operative nausea vomiting after cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 18-45 years Having informed consent Having ASA I and II Nulliparous Singleton pregnancy Patients with elective cesarean Patients with spinal anesthesia Patients with Pfannenstiel incision in surgery.
Exclusion criteria:
Underlying disease (i.e renal, liver, cardiac and pulmonary disease) History of allergy to the drugs of study Addiction or long term using of opiate Coagulopathy or use of anticoagulant drugs Disability for pain scoring Suffering from preeclampsia or HELLP or eclampsia or hepatitis Urgency cesarean section

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
To create simple random sequences web randomization (com.graphpad.www) dual group and for concealment, closed envelope method with random sequence (SNOSE) will be used.Random sequences will be recorded on the cards and then sequentally puted in the envelopes.In order to preserve random sequences the outer surface of the envelopes are numbered, respectively. Finally, the lid of the letter envelopes was pasted and it is placed inside the boxes, respectively.At the time of participants registration, one of the envelopes will be opened and the allocation group, will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients blindness: According to injecting of Dexamethasone in one group of study 30 minutes before spinal anesthesia, in another group distilled water will be injected to the patients in same time and measure. Researcher blindness: Drugs will be ordered by specialist, so the researcher who filled the check lists is blind.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Arak University of Medical Sciences

Street address
Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square

City
Arak

Province
Markazi

Postal code
3848176341

Approval date
2021-01-03, 1399/10/14

Ethics committee reference number
IR.ARAKMU.REC.1399.290

Health conditions studied

1

Description of health condition studied
Nausea and vomitting after cesarean

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Nausea happening after cesarean section untill 24 hours after surgery

Timepoint
In recovery room and 2,4,6,12,24 hours after surgery

Method of measurement
Asking of patient

2

Description
Vomitting score after cesarean section untill 24 hours after surgery

Timepoint
In recovery room and 2,4,6,12,24 hours after surgery
Method of measurement
VAS (Visual Analog Scale) score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:8 mg of Dexamethasone (Daroo pakhsh company) intravenously will be injected to the patients, 30 minutes before spinal anesthesia and 1 gr of Apotel (Exir company) intravenously will be injected immediately after spinal anesthesia.
Category
Treatment - Drugs

2

Description
Control group:2 cc of distilled water intravenously will be injected to the patients, 30 minutes before spinal anesthesia and 1 gr of Apotel (Exir company)intravenously will be injected immediately after spinal anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Dr Maryam Maktabi
Street address
West side of Emam Khomeini street, beside of gas company
City
Arak
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Markazi
Postal code
3816149369
Phone
+98 86 3277 6063
Email
It-taleghani@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
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Assistance of research and technology, Payambare azam institution, Arak University of Medical Sciences, Basij square
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research@arakmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Maryam Maktabi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Alireza Kamali

Position
Associate Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Valiasr hospital, Valiasr square

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Phone
086-32222003-8

Email
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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Shamim Valibak

Position
General physician non-faculty

Latest degree
Medical doctor

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