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 groups 1 gr of Apotel immediately after spinal anesthesia will be intravenously injected to the patients.

Main outcome variables
Vomiting 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)
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+98 86 3417 3502
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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
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 sequentially 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, Payambarazam 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

Description of health condition studied
Nausea and vomiting 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
Vomiting score after cesarean section until 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

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**Sponsors / Funding sources**

1

**Sponsor**
Name of organization / entity

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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**

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 updating data

Contact
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Latest degree
Medical doctor

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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