

# 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 divided 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 nausea 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 sequentially put 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 vomiting after cesarean

**ICD-10 code**

R11

**ICD-10 code description**

Nausea and vomiting

**Primary outcomes****1****Description**

Nausea happening after cesarean section until 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

##### City

Arak

##### Province

Markazi

##### Postal code

3816149369

##### Phone

+98 86 3277 6063

##### Email

lt-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

#### Street address

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

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Arak

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3848176341

#### Phone

+98 86 3417 3639

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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

##### Street address

West side of Emam Khomeini street, beside of gas company

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##### Phone

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##### Email

Dr.maryam.maktabi@gmail.com

## 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

**Street address**

Valiasr hospital, Valiasr square

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**Province**

Markazi

**Postal code**

3814957558

**Phone**

086-32222003-8

**Email**

alikalaliir@yahoo.com

## 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

**Street address**

Valiasr hospital, Valiasr square

**City**

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**Province**

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**Postal code**

3814957558

**Phone**

086-32222003-8

**Email**

sh.valibak@yahoo.com

## 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