

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison between Intravenous Acetaminophen (Apotel) and Diclofenac Suppository for Pain Management After elective second Cesarean Section at Imam Khomeini Hospital in Sari

Protocol summary

Study aim

Comparison between Intravenous Acetaminophen (Apotel) and Diclofenac Suppository for Pain Management After elective second Cesarean Section

Design

A clinical trial with a control group, with parallel groups, single-blind, randomized using table of random numbers, on 60 patients.

Settings and conduct

Imam Khomeini hospital in Sari

Participants/Inclusion and exclusion criteria

Women between the ages of 18 and 45 years; Full pregnancy time has passed; No chronic diseases such as cardiovascular, liver and kidney diseases; No drug addiction

Intervention groups

Intervention group 1: Diclofenac. Intervention group 2: Apotel.

Main outcome variables

Patients' vital signs (including respiratory rate, blood pressure, heart rate); nausea/vomiting; VAS (visual analog scale)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210816052199N1**
Registration date: **2021-08-31, 1400/06/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-31, 1400/06/09**

Update count: **0**

Registration date

2021-08-31, 1400/06/09

Registrant information

Name

Aghdas Ebadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3339 3850

Email address

a.ebadi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-17, 1400/05/26

Expected recruitment end date

2021-10-18, 1400/07/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between Intravenous Acetaminophen (Apotel) and Diclofenac Suppository for Pain Management After elective second Cesarean Section at Imam Khomeini Hospital in Sari

Public title

Comparison between Acetaminophen (Apotel) and Diclofenac

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

term pregnancies without past medical history without

addiction
Exclusion criteria:
allergy history(acetaminophen or local anesthesia agent)
kidney or liver disease opium addiction use of painless
medicine such as opium or NSAID or corticosteroids
diabets
Age
From **18 years** old to **45 years** old
Gender
Female
Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
After selecting 60 samples with inclusion criteria, the
samples will be assigned to two groups by blocking
method. The blocking process will be done by random
allocation software. With this software, 10 blocks of six
will be created and the samples will be entered into
study based on the numbers produced by the software.
Blinding (investigator's opinion)
Single blinded
Blinding description
The medicine will be prescribed to the patient by the
ward nurse and then the research evaluator will check
the effect of the medicine and have no information about
the type of medicine the patient is receiving.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical
Sciences

Street address

Imam khomeini hospital, Razi avenue

City

Sari

Province

Mazandaran

Postal code

4816633131

Approval date

2020-05-12, 1399/02/23

Ethics committee reference number

ir.mazums.rec.1399.192

Health conditions studied

1

Description of health condition studied

Pain control after cesarean section

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain after cesarean

Timepoint

Every 4 hours for up to 24 hours

Method of measurement

use of visual analog scale(VAS)

2

Description

nausea and vomiting

Timepoint

Every 4 hours for up to 24 hours

Method of measurement

asking the patient

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: After entering the ward, patients
will randomly receive 100 mg diclofenac suppository
from Abu Reihan Company and the patient's vital signs
and severity of pain, nausea and vomiting will be
recorded.If the pain intensity is more than 4, the patient
will receive up to three doses of the drug in 24 hours.

Category

Treatment - Drugs

2

Description

Intervention group2: After entering the ward, patients
will randomly receive 1000 mg of acetaminophen
injected by Daru Pakhsh Company. If the pain intensity is
more than 4, the patient will receive up to three doses of
the drug in 24 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Aghdas Ebadi

Street address

Imam khomeini hospital, Razi avenue

City

Sari

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Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Email

dr.jamkhane@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi

Street address

Moallem St. Deputy of Research and Research,

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Email

dr.jamkhane@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Aghdas Ebadi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ebadi Aghdas

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

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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

Part of the data, such as information about the main outcome

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Other than the conditions mentioned above, there is no special condition

From where data/document is obtainable

dr.jamkhane@gmail.com

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

After receiving the email, information will be sent to them within a maximum period of one month.

Comments