Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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)

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+98 11 3339 3850

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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeidi
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Moallem St.Deputy of Research and Research,
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4816633131
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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
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 updating data

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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