

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of intravenous acetaminophen effect with 24-hour and routine drip on control of pain in patients undergoing cesarean section

Protocol summary

Study aim

The aim of this study was to compare the effect of intravenous acetaminophen as a 24-hour drip or routine administration on pain control in patients undergoing cesarean section.

Design

A prospective double-blind randomized clinical trial; phase 3, with parallel groups; on 80 patients who were randomly assigned to the study and placed in groups A or B.

Settings and conduct

The statistical population of our study includes pregnant women who had been referred to Isfahan Family Hospital for cesarean section during 2018. All patients underwent routine GA or spinal anesthesia and then the patients were randomly divided into two groups. For one group, acetaminophen was administered as a 24-hour intravenous drip (group A) and for the other group, intravenous acetaminophen was administered routinely (group B). At the end, the results were analyzed with SPSS software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 16 to 40 years; ASA 1.2; Candidate for a cesarean section; Do not smoke or use opioids. Exclusion criteria: Sensitivity to any of the drugs used in the study; Having liver disease; History of seizures.

Intervention groups

Group A: 24-hour intravenous acetaminophen drip.
Group B: Routine intravenous acetaminophen injection.

Main outcome variables

Post Operative Pain; Blood Pressure; Heart Rate; Pain Killer Consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180708040381N3**

Registration date: **2022-02-17, 1400/11/28**

Registration timing: **retrospective**

Last update: **2022-02-17, 1400/11/28**

Update count: **0**

Registration date

2022-02-17, 1400/11/28

Registrant information

Name

Mehdi Izadi Zaman Abadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3272 4538

Email address

mimi_izadi2@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2017-10-23, 1396/08/01

Actual recruitment end date

2018-10-27, 1397/08/05

Trial completion date

2018-10-27, 1397/08/05

Scientific title

Comparison of intravenous acetaminophen effect with 24-hour and routine drip on control of pain in patients undergoing cesarean section

Public title

The effect of acetaminophen drip on pain after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 16 to 40 years Candidate for cesarean section No smoke and opioids consumption ASA class 1 or 2

Exclusion criteria:

Allergy to any of the drugs used in study Liver disease History of seizure

Age

From **16 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The women who met the inclusion criteria were randomly divided into two groups 1 and 2. In this way, the patients referred in group 1 on even days and the patients referred in group 2 on odd days.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients referred to each group as well as the person who recorded the patients' details did not know how to classify. The person taking the drip acetaminophen or acetaminophen routinely did not know which person was in group A or B. The researcher and the evaluator knew what the patient group was.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University , Najaf Abad Branch

Street address

Islamic Azad University, Najaf Abad Branch, University

Boulevard, Najaf Abad, Isfahan

City

Najaf Abad

Province

Isfahan

Postal code

8514143131

Approval date

2018-09-27, 1397/07/05

Ethics committee reference number

IR.IAU.NAJAFABAD.REC.1397.086

Health conditions studied

1

Description of health condition studied

post operative pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain Score

Timepoint

First 24 hr After Surgery Every 6 hr

Method of measurement

VAS Score

Secondary outcomes

empty

Intervention groups

1

Description

After the patient was fully conscious and in recovery in the 24-hour drip group, 2 mg / kg morphine and 4000 mg of acetaminophen were poured into the PCA pump and injected into the patient within 24 hours. Patients' VAS was evaluated in recovery at 6 hours, 12 hours, 18 hours and 24 hours after surgery, respectively. The acetaminophen used in this study was the so-called Apotel brand (manufactured in Greece and distributed by Koble Drug), which was used in 1000 mg ready-to-inject vials. The onset time of analgesic effect is 5 to 10 minutes and the maximum effect time is one hour and the duration of its effect is 4-6 hours. The PCA pump used was called Starmed, made in China, with a maintenance dose setting of 4 to 6 cc per hour with a 15-minute bolus interval for 24-hour acetaminophen drip.

Category

Treatment - Drugs

2

Description

In the routine intravenous acetaminophen group, only 2 mg / kg morphine was poured into the PCA pump and 1000 mg intravenous acetaminophen was injected into the patient every 6 hours.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Family hospital

Full name of responsible person

Mehran Gheibi MD

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Azad Islamic University, Najaf Abad Branch

Full name of responsible person

Farid Naimi

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Azad Islamic University, Najaf Abad Branch, University Boulevard, Najaf Abad

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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

Azad Islamic University, Najaf Abad Branch

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**

Esfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Izadi Zaman Abadi

Position

Anesthesiology Expert

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Position

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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

All content and study data will be shared after publication.

When the data will become available and for how long

Access will start from the time the article is published.

To whom data/document is available

All authors and managing director of the publication

Under which criteria data/document could be used

To use the contents of this study in dissertations or articles, Students and researchers have access to the documents of this study.

From where data/document is obtainable

Dr Mehdi Izadi Zaman Abadi Address: No6. Pirooz Building. North Mejmar Ave. Manoucheri Ave.Ferdoosi Ave Post Code: 8143834438 E-mail: mimi_izadi2@yahoo.com Tel: 00989131043958

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

Email or request will be read, and after consulting with other authors, the request will be reviewed and answered.

Comments