

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of effectiveness of intravenous Acetaminophen and Ketorolac with Fentanyl pump for post-cesarean pain control after spinal anesthesia

Protocol summary

Study aim

Comparison of the efficacy of intravenous acetaminophen and ketorolac with fentanyl pump in controlling post-cesarean pain following spinal anesthesia in pregnant women with cesarean delivery who will undergo cesarean section and spinal anesthesia in 2019

Design

A clinical trial with no control group, with parallel groups, no blinding, no randomization. The study will be a phase 3 clinical trial.

Settings and conduct

The study site will be Alavi Hospital. In this study, pregnant mothers who have cesarean section and will undergo cesarean section and spinal anesthesia will be included in the study. Patients will be randomly divided into two groups of 50. In the first group, the fentanyl pump will be divided into two groups of intravenous acetaminophen and ketorolac will be used. Effectiveness will be recorded in pain management of patients. Blindness has not been respected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with cesarean indication, 16 to 45 years old, patient consent for inclusion Exclusion criteria: Proven sensitivity to anesthetic drugs

Intervention groups

Intervention group 1: The recipient will receive the fentanyl pump. (20 cc fentanyl with 80 cc normal saline to a total volume of 100 cc by pain pump) Intervention group 2: will receive intravenous acetaminophen and ketorolac. (Three grams of apotel in 30 mg of ketorolac in total of 100 cc normal saline by pain pump)

Main outcome variables

The main variable of the study is the rate of pain after cesarean section.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190518043628N1**

Registration date: **2019-12-18, 1398/09/27**

Registration timing: **retrospective**

Last update: **2019-12-18, 1398/09/27**

Update count: **0**

Registration date

2019-12-18, 1398/09/27

Registrant information

Name

Maryam saadat Razavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 0739

Email address

m.r123456@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-31, 1397/11/11

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of intravenous Acetaminophen and Ketorolac with Fentanyl pump for post-cesarean pain control after spinal anesthesia

Public title

The effect of paracetamol and ketorolac with fentanyl pump on post-cesarean pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with cesarean indication Obtaining patient satisfaction

Exclusion criteria:

Previous proven sensitivity to anesthetics

Age

From **16 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

No. 1, Moallem Ave

City

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Province

Ardabil

Postal code

5613843973

Approval date

2019-08-10, 1398/05/19

Ethics committee reference number

IR.ARUMS.REC.1398.241

Health conditions studied

1

Description of health condition studied

Postoperative pain control cesarean section

ICD-10 code

ICD-10 code description

Delivery by emergency caesarean section

Primary outcomes

1

Description

Pain

Timepoint

Pain will be assessed at 2, 6, 12 and 24 hours after cesarean section.

Method of measurement

NRS (numerical rating scale) questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Pain control in the first group will be by fentanyl pump. (20 cc fentanyl with 80 cc normal saline to a total volume of 100 cc by pain pump)The pump speed will be 4 cc / h. All medicines will be provided by the Exir General Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Intervention group 2: Pain control in the second group was administered by a pump containing intravenous acetaminophen and ketorolac (three grams of apotel in 30 mg of ketorolac totaling one hundred cc normal saline by the pain pump).The pump speed will be 4 cc / h. All medicines will be provided by the Exir General Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi hospital

Full name of responsible person

Monire Hoseini

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Parvaneh Naftchi
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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
Ardabil 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
Tehran University of Medical Sciences
Full name of responsible person
Maryam saadat Razavi
Position
Assistant professor

Latest degree
Specialist
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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

The questionnaires will be made available anonymously and with a file number.

When the data will become available and for how long

After completing the study.

To whom data/document is available

University professors.

Under which criteria data/document could be used

In order to find out how to work in SPSS file, anonymous questionnaires will only be available with file number.

From where data/document is obtainable

Contact Dr. Maryam saadat Razavi.

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

Information is available after contacting Dr. Maryam saadat Razavi and University approval.

Comments