Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
Ardabil
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
Street address

No. 1, Moallem Ave
City
Ardabil
Province
Ardabil
Postal code
5613843793
Phone
+98 45 3323 0739
Fax
Email
meisamfooladi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Parvaneh Naftchi
Street address
No. 1, DAneshgah Ave
City
Ardabil
Province
Ardabil
Postal code
5613843998
Phone
+98 45 3323 0739
Email
meisamfooladi@gmail.com
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
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No. 1, Moallem Ave
City
Ardabil
Province
Ardabil
Postal code
5613843796
Phone
+98 45 3323 0739
Email
meisamfooladi@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Maryam saadat Razavi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
No. 1, Moallem Ave
City
Ardabil
Province
Ardabil
Postal code
5613843793
Phone
+98 45 3323 0739
Email
meisamfooladi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Ahmad Ghazi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
No. 1, Moallem Ave
City
Ardabil
Province

Ardabil
Postal code
5613843698
Phone
+98 45 3323 0739
Email
meisamfooladi@Gmail.com

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