Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the effectiveness of intramuscular injection of Ketorolac with PCA pump Containing Morphine and Apotel in Pain control of Patients after Cesarean Section

Protocol summary

Study aim

Comparison of the effectiveness of intramuscular ketorolac with PCA pump containing morphine and Apotel in pain control of patients after cesarean section.

Design

Clinical trial with parallel groups, double-blind, randomized, phase 2 on 90 patients. For randomization, block method and homogenization of blocks of four were used

Settings and conduct

This study was conducted on pregnant mothers scheduled for elective caesarean section under general anesthesia at Valiasr Hospital in Birjand, with no exclusion criteria. After surgery, patients were given pain assessments using a visual pain score 15 minutes after entering the recovery room. They were then divided into two groups: 1. Group A: Patients received a deep intramuscular injection of 30 mg if they weighed under 50 kg or 60 mg if they weighed over 50 kg of a medication, repeated every 8 hours. 2. Group B: Patients received a combination of 0.5 mg/kg of morphine and 40 mg/kg of Apotel through an anesthesia pump. Pain assessments were conducted at 6, 12, and 24 hours after the operation, and patients' responses were recorded. Additionally, the patients were examined for any adverse side effects.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant mothers aged 20-40 years with ASA class 1-2 with a gestational age of at least 37 weeks; candidates for elective cesarean section with a transverse incision. Exclusion criteria: coagulation disorders; Receiving NSAID and narcotics before surgery; BMI more than 30.

Intervention groups

Group A (receiver of intramuscular ketorolac) and group B (receiver of PCA pump containing morphine and Apotel)

Main outcome variables

Average pain intensity of patients ؛ average hemodynamic indices ؛ frequency distribution of side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231005059625N1**
Registration date: **2023-10-25, 1402/08/03**
Registration timing: **prospective**

Last update: **2023-10-25, 1402/08/03**
Update count: **0**

Registration date

2023-10-25, 1402/08/03

Registrant information

Name

Mersede Faghihshojaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 5000

Email address

m.faghihshojaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-11-21, 1403/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of intramuscular injection of Ketorolac with PCA pump Containing Morphine and Apotel in Pain control of Patients after Cesarean Section

Public title

Comparison of the effectiveness of intramuscular injection of Ketorolac with PCA pump Containing Morphine and Apotel in Pain control of Patients after Cesarean Section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant mothers, 20-40 years old, Elective caesarean section with transverse incision Pregnancy age at least 37 weeks American Society of Anesthesiology based on II and I ASA class

Exclusion criteria:

Suffering from gestational hypertension Receiving NSAID and narcotics before surgery Mothers of macrosomic and multiple babies Spinal or epidural anesthesia method history of peptic ulcer history of coagulation disorders BMI more than 30

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to enter the study, the basic information of the patient is recorded in the relevant forms. The referring patients were divided into two groups A (recipients of intramuscular ketorolac) and group B (recipients of PCA pump containing morphine and Apotel) by a simple random block method and homogenization of quadruple blocks (BAAB, ABBA, BABA, ABAB, BBAA, AABB).

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the mothers, they will be aware of the generalities of the research, which is the creation of analgesia by drugs, but they will not know about the method of prescribing drugs based on the groups under study. 15 minutes after entering the recovery room and before the intervention to create analgesia, the patient's pain is measured and recorded based on the visual pain score (VAS). Then, for the patients 6, 12 and 24 hours after the operation, the questionnaire is completed by one of the trained nurses who is not part of the research team and is not aware of the groups under study. (It should be noted that in the patient questionnaire, the type of prescription drug is mentioned as group A and group B, and the nurse entering the data is not aware of the type of prescription drug.)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Birjand University of Medical Sciences

Street address

Ghaffari Blvd, Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۰۷۶

Approval date

2023-09-25, 1402/07/03

Ethics committee reference number

IR.BUMS.REC.1402.278

Health conditions studied

1

Description of health condition studied

Painlessness after surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Determination and comparison of the average pain intensity of the patients after the cesarean section in the group receiving intramuscular ketorolac and the group receiving morphine and Apotel by PCA pump

Timepoint

, 15 minutes after the operation (before intervention for

analgesia) and 6, 12 and 24 hours after the cesarean section

Method of measurement

Visual pain score(Visual Analogue Scale)

Secondary outcomes

1

Description

The mean of hemodynamic indices (average blood pressure, heart rate and SPO2).

Timepoint

15 minutes after the operation (before intervention for analgesia) and 6, 12 and 24 hours after the operation

Method of measurement

Automatic monitoring device

2

Description

Frequency distribution of mothers' need to receive an additional dose of anesthesia

Timepoint

In the first 24 hours after the operation

Method of measurement

Based on the history of the patient

3

Description

Frequency distribution of side effects (nausea, vomiting, abnormal sleepiness, respiratory depression, stomach pain)

Timepoint

In the first 24 hours after the operation

Method of measurement

Based on the history of the patient

Intervention groups

1

Description

Intervention group1: Intervention Group: In the intervention group, an Optofuser analgesia pump from Darman Gostar Sepano in Iran was used. This pump had a capacity of 100 cc and operated at a speed of 4 cc per hour. A bolus dose of 0.5 cc could be administered with a 15-minute lockout period. The medication administered through this pump consisted of 0.5 mg per kilogram of morphine combined with 40 mg per kilogram of Apotel, and it was diluted with normal saline to reach a total volume of 100 cc.

Category

Treatment - Drugs

2

Description

Intervention group2: Intervention group: Ketorolac, 30 mg in people under 50 kg and 60 mg in people over 50 kg as a deep intramuscular injection that is repeated every 8 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Mersede Faghih Shojaei

Street address

Ghafari Street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3162 2000

Fax

+98 56 3163 5801

Email

amoozesh@bums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Masoud Yousefi

Street address

Ghafari Blvd

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3238 1200

Fax

+98 56 3238 1220

Email

masoud.yousefi@bums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Mersede Faghihshojaei

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Ghaffari blv - Birjand university of medical science

City

Birjand

Province

South Khorasan

Postal code

۹۷۱۷۸۵۳۰۷۶

Phone

+98 56 3238 5000

Fax

Email

m.faghihshojaei@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mersede Faghihshojaei

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Ghaffari blv - Birjand university of medical science

City

Birjand

Province

South Khorasan

Postal code

9717853076

Phone

+98 56 3238 5000

Fax

Email

m.faghihshojaei@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Mersede Faghihshojaei

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Ghaffari blv - Birjand university of medical science

City

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Province

South Khorasan

Postal code

9717853076

Phone

+98 56 3238 5000

Fax

Email

m.faghihshojaei@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Protocol for the treatment of pain after cesarean section

When the data will become available and for how long

After the publication of the article

To whom data/document is available

Researchers of all disciplines

Under which criteria data/document could be used

After the publication of the article

From where data/document is obtainable

m.faghihshojaei@gmail.com

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

m.faghihshojaei@gmail.com

Comments