

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of the preemptive effect of Ketorolac (IV) versus Meperidine on shivering and pain after cesarean section under spinal anesthesia

Protocol summary

Summary

Objectives: To compare the preemptive effect of intravenous Ketorolac versus Meperidine (Pethedine) on shivering and pain after cesarean section surgery under spinal anesthesia. Design: A prospective, randomized, duple-blinded, placebo-controlled clinical trial in Kowsar teaching hospital. Setting and conduct: Tympanic temperature, mean arterial pressure, pulse rate and shivering severity recorded 10 minute before intrathecal injection, end of operation and every 30 minute until 1 hour in recovery room. The 24 hours Post operative Pain severity is classified in numerical scale and analgesic (Apotel) given if needed. First time and total dose of administered analgesic would be compared. Participants: 150 ASA physical status 1, 2 pregnant women, scheduled for elective cesarean section enrolled in this study and excluded if existing history of asthma; peptic ulcer; renal; hepatic or hemorrhagic disease; consumption or history of hypersensitivity reaction to Opioid; NSAIDs or other analgesics and MAOIs. Interventions: Patients randomized to three groups: First group 30 mg intravenous Ketorolac (n=50), second group 50 mg intravenous Pethedine (n=50), third group 2 ml Normal saline (n=50). Main outcome measure variables: Shivering and Pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104073051N4**

Registration date: **2016-04-24, 1395/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-24, 1395/02/05

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the preemptive effect of Ketorolac (IV) versus Meperidine on shivering and pain after cesarean section under spinal anesthesia

Public title

Comparison of the preemptive effect of Ketorolac (IV) versus Pethidine on shivering and pain after cesarean section under spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women who candidate for

elective cesarean section; ASA class 1,2. Exclusion criteria: History of asthma; peptic ulcer; renal; hepatic or hemorrhagic disease; Consumption or history of sensitivity reaction to opioid; NSAIDs or other analgesics and MAOIs.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Qazvin University of Medical Sciences

Street address

Bahonar Blvd, Qazvin, Iran

City

Qazvin

Postal code

Approval date

2015-02-04, 1393/11/15

Ethics committee reference number

28/20/9850

Health conditions studied

1

Description of health condition studied

Complications predominantly related to the puerperium

ICD-10 code

O89.5

ICD-10 code description

Other complications of spinal and epidural anaesthesia during the puerperium

Primary outcomes

1

Description

Shivering

Timepoint

10 minute before anesthesia, end of surgery and every 30 minute until an hour.

Method of measurement

Vision and medical records

2

Description

Pain

Timepoint

Until 24 hours post operation

Method of measurement

VAS (Visual Analogue Scale)

Secondary outcomes

1

Description

Temperature

Timepoint

10 minute before anesthesia, end of surgery and every 30 minute until an hour.

Method of measurement

Thermometry from tympanic membrane

2

Description

Blood pressure

Timepoint

10 minute before anesthesia, end of surgery and every 30 minute until an hour.

Method of measurement

With manometry from brachial artery

3

Description

Pulse rate

Timepoint

10 minute before anesthesia, end of surgery and every 30 minute until an hour.

Method of measurement

With monitoring

Intervention groups

1

Description

First group received 50 mg intravenous Meperidine

Category

Treatment - Drugs

2

Description

Second group received 30 mg intravenous Ketorolac

Category

Treatment - Drugs

3

Description

Third group received 2 CC intravenous Normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Dr. Marziyeh Beigom Khezri

Street address

Kowsar Hospital, Taleghani street, Qazvin, Iran

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Naser Taghi Poor Farivar

Street address

Bahonar Blvd, Qazvin, Iran

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Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Maryam Alsadat Mosallaei

Position

Anesthesiology Asistant

Other areas of specialty/work

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Position

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Other areas of specialty/work

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Full name of responsible person

Dr. Marziyeh Beigom Khezri

Position

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Other areas of specialty/work

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Fax**Email**mkhezri@qums.ac.ir; mkhezri88@gmail.com;
m.mosallaei93@gmail.com**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)***empty***Study Protocol***empty***Statistical Analysis Plan***empty***Informed Consent Form***empty***Clinical Study Report***empty***Analytic Code***empty***Data Dictionary***empty*