# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Comparision 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, duble-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 hypersensivity 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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Marzieh Khezri
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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**

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

**Public title**

Comparision 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**
Thermometriy 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 manometriy 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
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## 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

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*