

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of prophylactic use ketorolac with pethidine for prevention of shivering and pain after cesarean section under spinal anesthesia

Protocol summary

Study aim

Comparison of prophylactic use ketorolac with pethidine for prevention of shivering and pain after cesarean section under spinal anesthesia

Design

A clinical trial with parallel, double-blind, randomized by randomizer website, phase 3 was performed on 90 patients in the three equal groups.

Settings and conduct

Phase 3 clinical trial with three parallel groups was performed on 90 patients referred to Shahid Motahari Hospital in Urmia. Patients were enrolled in three equal groups (ketorolac = 30 people, pethidine=30 people and normal saline = 30people). In this study, patients and clinical assessor as well as statistical analyzers were unaware of group assignment. Randomization was done by randomizer website.

Participants/Inclusion and exclusion criteria

Inclusion criteria were age between 18 to 40 years old, American Society of Anesthesiologists (ASA) I and II and candidate for cesarean. Exclusion criteria were dissatisfaction to participate in the study and sensitivity to Non-steroidal anti-inflammatory drugs (NSAIDs)

Intervention groups

Intervention group 1: Intravenous ketorolac Intervention group 2: Intravenous pethidine Control group: normal saline

Main outcome variables

Shivering and pain after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201207049639N2**

Registration date: **2020-12-30, 1399/10/10**

Registration timing: **retrospective**

Last update: **2020-12-30, 1399/10/10**

Update count: **0**

Registration date

2020-12-30, 1399/10/10

Registrant information

Name

Hadi Houshyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

hooshyar.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-23, 1398/09/02

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

2020-04-27, 1399/02/08

Actual recruitment end date

2020-11-05, 1399/08/15

Trial completion date

2020-11-05, 1399/08/15

Scientific title

Comparison of prophylactic use ketorolac with pethidine for prevention of shivering and pain after cesarean section under spinal anesthesia

Public title

Effect of prophylactic use ketorolac with pethidine for prevention of shivering and pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 to 40 years old American Society of Anesthesiologists (ASA) I and II Candidate for cesarean

Exclusion criteria:
Dissatisfaction to participate in the study Sensitivity to Non-steroidal anti-inflammatory drugs (NSAIDs)

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Women candidates for cesarean section were randomly divided into three groups receiving pethidine, ketorolac and normal saline using <https://www.randomizer.at/>.

Blinding (investigator's opinion)
Double blinded

Blinding description
Women were unaware of being in intervention groups. After spinal anesthesia, the drug is injected intravenously in a normal syringe because both drugs are colorless, so the patient is not able to identify the type of drug, so she is blind, and the statistical analyzer also Received the data as code A and B for the intervention and control groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences

Street address
Urmia University of Medical Sciences, Resalat Street, Jahad Ave., Urmia, Iran

City
Urmia

Province
West Azarbaijan

Postal code

5714783734

Approval date
2019-11-20, 1398/08/29

Ethics committee reference number
IR.UMSU.REC.1398.321

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
G89.1

ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description
Pain

Timepoint
At recovery, one hour after surgery, 24 hours after surgery

Method of measurement
Visual analogue Scale (VAS)

2

Description
Shivering

Timepoint
At recovery

Method of measurement
observation (Having / not having shivering)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In the first intervention group, patients received 30 mg of intravenous Ketorolac (Produced by Caspian) 10 minutes before spinal anesthesia.

Category
Treatment - Drugs

2

Description
Intervention group 2: In the second intervention group, patients received 50 mg of intravenous pethidine (Produced by Caspian) 10 minutes before spinal anesthesia.

Category

Treatment - Drugs

3

Description

Control group: In the control group, patients received 5 cc of normal intravenous saline 10 minutes before spinal anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Motahari Hospital

Full name of responsible person

Dr. Hadi Hooshyar

Street address

Shahid Motahhari hospital; Kashani street, Urmia, Iran.

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Urmia

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Postal code

5714783734

Phone

+98 44 3198 8293

Email

hooshyar.h@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences; Resalat street; Jihad Blvd; Urmia; Iran.

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mohebbi.i@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hadi Hooshyar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Shahid Motahhari Hospital; Kashani street; Urmia; Iran.

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Person responsible for scientific inquiries

Contact

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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

Information can be provided without patients' names

When the data will become available and for how long

A teat after the completion of the study

To whom data/document is available

Faculty researchers

Under which criteria data/document could be used

Just research

From where data/document is obtainable

Email to Dr. Hoshyar

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

Email to Dr. Hoshyar

Comments