

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparison of the effect of adding pethidine to bupivacaine and half of ropivacaine on the severity of pain in women referred to Motahari Hospital during elective cesarean section.

#### Protocol summary

##### Study aim

Comparison of the effect of adding pethidine to half-percent bupivacaine and half-percent ropivacaine on pain intensity in women undergoing elective cesarean section

##### Design

This study will be a double-blind randomized clinical trial with parallel groups on 60 patients referred to Motahhari Hospital who are undergoing cesarean section. Patients participating in the study will be divided into two groups by tossing coins.

##### Settings and conduct

Patients referred to Motahhari Hospital in Jahrom who will undergo cesarean section will be included in the study. Patients participating in the study will be divided into two groups of bupivacaine and ropivacaine by throwing coins. The person participating in the study, the researcher and the data collector will be unaware of the type of drug used.

##### Participants/Inclusion and exclusion criteria

Admission requirements: All women referred to Motahhari Hospital in Jahrom who underwent cesarean section and expressed their consent to participate in the study. Non-entry conditions: includes patients who do not have hemodynamic stability and suffer from acute and chronic pain.

##### Intervention groups

Intervention group1: received 12/5 mg bupivacaine + 10 mg pethidine intrathecally. Intervention group 2: receive 15 mg of ropivacaine + 10 mg of pethidine intrathecally.

##### Main outcome variables

Pain

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20210415050976N10**

Registration date: **2022-02-19, 1400/11/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-19, 1400/11/30**

Update count: **0**

#### Registration date

2022-02-19, 1400/11/30

#### Registrant information

##### Name

navid kalani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 5433 6085

##### Email address

k.navid@juma.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2021-11-01, 1400/08/10

#### Expected recruitment end date

2022-08-01, 1401/05/10

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the effect of adding pethidine to bupivacaine and half of ropivacaine on the severity of

pain in women referred to Motahari Hospital during elective cesarean section.

#### Public title

Comparison of the effect of adding pethidine to half-percent bupivacaine and half-percent ropivacaine on pain intensity in women undergoing elective cesarean section

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Hemodynamic stability Not having infection at the site of needle entry Not having High intracranial pressure Not having coagulation disorders

##### Exclusion criteria:

History of addiction Allergy to drugs Obesity

#### Age

From **17 years** old to **45 years** old

#### Gender

Female

#### Phase

3

#### Groups that have been masked

- Participant
- Investigator
- Outcome assessor

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

In this study, block randomization method is used. With the help of the online site ([www.sealedenvelope.com/simple-randomiser/v1/lists](http://www.sealedenvelope.com/simple-randomiser/v1/lists)) randomization, 2 blocks of 30 are created. In each randomly assigned block, 30 patients are assigned to the bupivacaine group and 30 patients to the ropivacaine group.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

For blinding in the present study, the double-blind method is used, so that 1- the person who examines the results and 2- the person who performs the injections do not know which patient received ropivacaine or bupivacaine.

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Jahrom University of Medical Sciences

##### Street address

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

##### City

Jahrom

##### Province

Fars

##### Postal code

7167758256

##### Approval date

2020-09-02, 1399/06/12

##### Ethics committee reference number

IR.JUMS.REC.1399.074

### Health conditions studied

#### 1

#### Description of health condition studied

Cesarean section

#### ICD-10 code

O75.82

#### ICD-10 code description

Onset (spontaneous) of labor after 37 completed weeks of gestation but before 39 completed weeks gestation, with delivery by (planned) cesarean section

### Primary outcomes

#### 1

#### Description

Pain

#### Timepoint

When entering the operating room, when entering the recovery, leaving the recovery, 2 hours after the operation, 6 hours after the operation, 12 hours after the operation and 24 hours after the operation

#### Method of measurement

Visual scale of pain

### Secondary outcomes

#### 1

#### Description

Blood pressure changes

#### Timepoint

Before the operation, before the spinal, immediately after the spinal, after the baby is born and then every 10 minutes until the end of the operation, when entering the recovery, when leaving the recovery)

#### Method of measurement

monitoring

## 2

### **Description**

Heart Rate

### **Timepoint**

Before the operation, before the spinal, immediately after the spinal, after the baby is born and then every 10 minutes until the end of the operation, when entering the recovery, when leaving the recovery)

### **Method of measurement**

monitoring

## **Intervention groups**

### 1

#### **Description**

Intervention group: 12/5mg of bupivacaine as a local anesthetic made by Abu Reihan Pharmaceutical Company + 10 mg of pethidine as a narcotic made by Elixir Pharmaceutical Company Received intrathecally.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Intervention group 1: 15 mg of ropivacaine as a local anesthetic made by Abu Reihan Pharmaceutical Company + 10 mg of pethidine as a narcotic made by Elixir Pharmaceutical Company Received intrathecally.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Motahhari Hospital of Jahrom city

##### **Full name of responsible person**

Navid Kalani

##### **Street address**

Jahrom, Shahid Motahari Boulevard, Motahari Hospital

##### **City**

Jahrom

##### **Province**

Fars

##### **Postal code**

71677251542

##### **Phone**

+98 71 3525 5652

##### **Email**

Navidkalani@ymail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Jahrom University of Medical Sciences

#### **Full name of responsible person**

Sol Joo Kavous

#### **Street address**

Jahrom, Shahid Motahari Boulevard, Jahrom University of Medical Sciences, Vice Chancellor for Research

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+98 71 2536 5231

#### **Email**

navidkalani@ymail.com

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Jahrom 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**

Jahrom University of Medical Sciences

##### **Full name of responsible person**

Navid Kalani

##### **Position**

Research Expert

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Anesthesiology

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k.navid@jums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Jahrom University of Medical Sciences

**Full name of responsible person**

Navid Kalani

**Position**

Research Expert

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for updating data

### Contact

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Jahrom University of Medical Sciences

**Full name of responsible person**

Navid Kalani

**Position**

Research Expert

**Latest degree**

Bachelor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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**

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

**Data Dictionary**

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