

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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) 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 bupivacaine 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	

<u>1</u>	
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	
<u>1</u>	
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	
<u>1</u>	
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	
<u>1</u>	
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

Motahari Hospital of Jahrom city

Full name of responsible person

Navid Kalani

Street address

Jahrom, Shahid Motahari Boulevard, Motahari Hospital

City

Jahrom

Province

Fars

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71677251542

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+98 71 3525 5652

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Navidkalani@gmail.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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Jahrom

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Phone

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Email

navidkalani@gmail.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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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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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

Person responsible for updating data

Contact

Name of organization / entity

Jahrom University of Medical Sciences

Full name of responsible person

Navid Kalani

Position

Research Expert

Latest degree

Bachelor