Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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
City
Jahrom
Province
Fars
Postal code
7167758256
Phone
+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
Street address
Jahrom, Shahid Motahari Boulevard
City
Jahrom
Province
Fars
Postal code
7167758256
Phone
+98 71 2536 5231
Email
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
Street address
Jahrom, Shahid Motahari Boulevard
City
Jahrom
Province
Fars
Postal code
7167758256
Phone
+98 71 2536 5231
Email
k.navid@jums.ac.ir

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
Other areas of specialty/work
Anesthesiology
Street address
Jahrom, Shahid Motahari Boulevard
City
Jahrom
Province
Fars
Postal code
7167758256
Phone
+98 71 2536 5231
Email
k.navid@jums.ac.ir

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