Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of two different doses of intrathecal ropivacaine on onset and duration of sensory and motor block in patients undergoing cesarean section with spinal anesthesia

Protocol summary

Study aim

Comparison of two different doses of intrathecal ropivacaine on onset and duration of sensory and motor block in patients undergoing cesarean section with spinal anesthesia

Design

A randomized double-blind clinical trial, with parallel groups, phase 3 on 66 patients. A table of random numbers is used for randomization.

Settings and conduct

66 patients who are candidates for cesarean section who refer to Shahid Sadoughi Hospital in Yazd are randomly divided into two equal groups: Patients received 20 mg ropivacaine (group 1) and patients received 30 mg ropivacaine (group 2). The syringes were prepared and coded by a collaborator with the same volume equal to 6 cc. Half of the syringes contained 30 mg of 0.5% rupivocaine and the other half contained 20 mg of rupivocaine 0.5% and 2 cc of normal saline. For all patients, hemodynamic variables including systolic, diastolic and mean arterial blood pressure were measured every 3 minutes until birth and then every 5 minutes until the end of surgery. Pin-prick test was used to assess the sensory level and modified Bromage scale was used to assess the motor block.

Participants/Inclusion and exclusion criteria

Inclusion criteria were women aged 18-40 with term pregnancy and ASA (American Society of Anesthesiologists) Class 1 and candidates for non-emergency cesarean section under the spinal anesthesia. Exclusion criteria were: patient dissatisfaction with entering the study, fetal anomalies, and heart, liver, kidney or cerebrovascular diseases, preeclampsia, eclampsia, weighing less than 50 kg or more than 100 kg, sensitivity to any of the drugs used in the study

Intervention groups

patients received 20 mg ropivacaine and patients received 30 mg ropivacaine

Main outcome variables

Faster and longer sensory and motor blocks and higher surgeon satisfaction with higher doses of intrathecal ropivacaine, without any side effects

General information

Reason for update

Acronym

ASA

IRCT registration information

IRCT registration number: **IRCT20210114050036N1**
Registration date: **2021-04-17, 1400/01/28**
Registration timing: **retrospective**

Last update: **2021-04-17, 1400/01/28**
Update count: **0**

Registration date

2021-04-17, 1400/01/28

Registrant information

Name

mojdeh niknafs

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3725 8222

Email address

mh.yavari@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date
2019-03-06, 1397/12/15
Actual recruitment start date
2018-09-23, 1397/07/01
Actual recruitment end date
2019-03-06, 1397/12/15
Trial completion date
2019-03-06, 1397/12/15

Scientific title
Comparison of two different doses of intrathecal ropivacaine on onset and duration of sensory and motor block in patients undergoing cesarean section with spinal anesthesia

Public title
Comparison of two different doses of intrathecal ropivacaine in patients undergoing cesarean section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Term pregnancy ASA Class 1 Candidates for non-emergency cesarean section under the spinal anesthesia
Exclusion criteria:
Fetal anomalies Heart, liver, kidney or cerebrovascular diseases Preeclampsia and eclampsia Weighting less than 50 kg or more than 100 kg Sensitivity to any of the drugs used in the study For any reason that the patient needs general anesthesia Patient dissatisfaction for entering to the study
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **66**
Actual sample size reached: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
This clinical trial was designed by simple randomization using a random number table. The project partner placed participants with even random numbers in the intervention group (30 mg rupivacaine) and participants with odd random numbers in the control group (20 mg rupivacaine) in order of entry of participants.
Blinding (investigator's opinion)
Double blinded
Blinding description
After obtaining informed consent, participants were placed in group 1 or 2 by a project partner using a random number table. The participant and the researcher did not know any of the assignments in the groups. Rupivacaine-containing syringes were prepared and coded by a design partner with an equal volume of 6 cc. Half of the syringes contained 30 mg of 0.5% ropivacaine with a volume of 6 cc and the other half contained 20 mg of 0.5% ropivacaine and 2 cc of normal saline with a volume of 6 cc. During the project, depending on the assignment of the participant to group 1 or 2, the project partner, as the only informed person, delivers the syringe containing rupivacaine (20 or 30 mg) to the researcher for intrathecal injection. Therefore, the specialist physician did not know the concentration of rupivacaine in the syringes and evaluated the patients during the study.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Yazd Shahid Sadoughi University of Medical Sciences
Street address
No. 6, Etehadieh Ave, Shahid Sadooghi Blvd
City
Yazd
Province
Yazd
Postal code
8917697145
Approval date
2018-06-26, 1397/04/05
Ethics committee reference number
IR.SSU.MEDICINE.REC.1397.053

Health conditions studied

1

Description of health condition studied
Investigation of the onset and duration of sensory and motor blocks in the administration of two different doses of intrathecal ropivacaine
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Onset and duration of sensory block

Timepoint

Examine the sensory level in first minute and then every 2 minutes to 15 minutes and then every 15 minutes to an hour, then every 10 minutes until the sensory level returns to T10

Method of measurement

Pin-prick test using a 22 Gauge needle

2

Description

Onset and duration of motor block

Timepoint

Investigation of the motor block in first minute and then every 2 minutes to 15 minutes and then every 15 minutes to an hour, then every 10 minutes until motor block return to a scale lower than the maximum movement block created

Method of measurement

Modified Bromage scale

Secondary outcomes

1

Description

Systolic, diastolic and mean arterial pressure

Timepoint

At the beginning of study (before the intervention) and then every 3 minutes until the baby was born and then every 5 minutes until the end of surgery

Method of measurement

Non-invasive blood pressure monitoring

2

Description

Heart rate

Timepoint

Continuously from the beginning of the study (before the intervention) until the end of surgery

Method of measurement

Electrocardiogram monitoring

Intervention groups

1

Description

Intervention group: 30 mg rupivocaine 0.5% made by Molteni company with a volume of 6 cc was injected intrathecally in the L4-L5 space

Category

Other

2

Description

Intervention group: 20 mg rupivocaine 0.5% made by Molteni company with 2 cc of normal saline, in a syringe with a volume of 6 cc was injected intrathecally inL4-L5 space

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Shahid Sadoughi hospital

Full name of responsible person

Mojdeh Niknafs

Street address

No. 6, Etehadieh Ave, Shahid Sadooghi Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaee

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Mojdeh Niknafs
Position
Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data are shareable after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the publication of the results
To whom data/document is available
Data will be available to researchers working in academic and scientific institutions
Under which criteria data/document could be used
Studied data can be used to compare with similar researches
From where data/document is obtainable
Refer to the e-mail, dr.m.niknafs@gmail .com
What processes are involved for a request to access data/document
After sending the reason for the request for data files and reviewing it, the documents will be sent within two

weeks	**Comments**