Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Jul 2026

The comparison of duration of analgesia after cesarean section under spinal anesthesia with Ropivacaine-Fentanyl and Ropivacaine-Sufentanil

Protocol summary

Study aim
The comparison of duration of analgesia after cesarean section under spinal anesthesia with Ropivacaine-Fentanyl and Ropivacaine-Sufentanil

Design
This is a clinical trial study with parallel groups, double-blinded randomized, will be conducted on 44 women undergoing cesarean section with spinal anesthesia. Assignment of patients to the study groups will be done by random-numbers table and using computer.

Settings and conduct
From pregnant women candidate for cesarean section with spinal anesthesia referring to Imam Khomeini hospital, Ahvaz, total of 44 patients will be selected and randomly divided into 2 groups. The patients and experimenters will not know about type of treatment and patient grouping and thus until the end of trial the study will be remained double-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 17 to 45 years old; ASA Class I and II; being candidate for elective cesarean section; no drug allergies to fentanyl, sufentanil and ropivacaine; no history of addiction; consent to participate in the study. Exclusion criteria: severe liver disease; duration of surgery more than 90 minutes; bleeding volume more than 1500 cc during surgery; need for general anesthesia.

Intervention groups
In the first Intervention group, Ropivacaine 5 mg/cc (Aburaihan pharmaceutical Co., Iran) with fentanyl 25 µg (Aburaihan Co., Iran) with volume of 4 mL will be injected for spinal anesthesia. In the second Intervention group: Ropivacaine 5 mg/cc (Aburaihan pharmaceutical Co., Iran) with sufentanil 2.5 µg (Aburaihan Co., Iran) with volume of 4 mL will be injected for spinal anesthesia.

Main outcome variables
Duration of analgesia,; hemodynamic changes including systolic blood pressure, diastolic blood pressure and presence of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210827052297N1**
Registration date: **2021-09-06, 1400/06/15**
Registration timing: **prospective**

Last update: **2021-09-06, 1400/06/15**
Update count: **0**

Registration date
2021-09-06, 1400/06/15

Registrant information

Name
Atusa Ahmadi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3001 3374

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aahmadi@ajums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-23, 1400/07/01

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The comparison of duration of analgesia after cesarean section under spinal anesthesia with Ropivacaine-Fentanyl and Ropivacaine-Sufentanil

Public title
Duration of analgesia after cesarean section with Ropivacaine-Fentanyl and Ropivacaine-Sufentanil
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 17 to 45 years old ASA Class I and II Candidate for elective cesarean section No allergies to fentanyl, sufentanil and ropivacaine no history of addiction Consent to participate in the study
Exclusion criteria:
Severe liver disease Need for general anesthesia
Age
From **17 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned into two groups by simple randomization method. Allocation of patients to the study groups will be done by random-numbers table and using computer, and on this basis patients will be included in one of the two treatment groups. The implementation of the random allocation sequence occurs without knowledge of which patient will receive which treatment.
Blinding (investigator's opinion)
Double blinded
Blinding description
Intervention (receiving fentanyl or sufentanil with ropivacaine) and patient evaluation will be carried out by a physician who is blinded to placement in treatment groups. Also patients and statistical analyzer will not know about patient grouping.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
City
Ahvaz
Province
Khouzestan
Postal code
6135733118
Approval date
2021-08-14, 1400/05/23
Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1400.084

Health conditions studied

1

Description of health condition studied
Pain after cesarean section
ICD-10 code
G89
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Duration of analgesia
Timepoint
After entering the recovery room, then every 15 minutes until the first hour, then every hour for 12 hours
Method of measurement
The duration of analgesia is the time of performing spinal anesthesia to Visual analog scale (VAS) grade 3

2

Description
Systolic blood pressure
Timepoint
At the beginning of the study (before the intervention) and then every 5 minutes until end of recovery
Method of measurement
Mercury barometer

3

Description
Diastolic blood pressure
Timepoint
At the beginning of the study (before the intervention) and then every 5 minutes until end of recovery
Method of measurement
Mercury barometer

Secondary outcomes

1

Description
Nausea after surgery
Timepoint
In the first 12 hours after surgery
Method of measurement
Presence of nausea based on direct observation and patients report

2

Description
Vomiting after surgery
Timepoint
In the first 12 hours after surgery
Method of measurement
Presence of vomiting based on direct observation and patients report

Intervention groups

1

Description
Intervention group: Ropivacaine 5 mg/cc (Aburaihan pharmaceutical CO., Iran) with fentanyl 25 µg (Aburaihan CO., Iran) with volume of 4 mL will be injected for spinal anesthesia.
Category
Treatment - Drugs

2

Description
Intervention group: Ropivacaine 5 mg/cc (Aburaihan pharmaceutical CO., Iran) with sufentanil 2.5 µg (Aburaihan CO., Iran) with volume of 4 mL will be injected for spinal anesthesia.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Atusa Ahmadi
Street address
Imam Khomeini Hospital, Azadegan St.
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6193673111
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Badavi
Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
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badavim@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Atusa Ahmadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd.
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Resident

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Person responsible for updating data

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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