Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of the efficacy of bupivacaine in combination with sufentanil or bupivacaine in combination with meperidine or bupivacaine alone in spinal anesthesia in patients undergoing elective cesarean section

Protocol summary

Study aim

Aim was comparison efficacy of bupivacaine in combination with sufentanil or bupivacaine in combination with meperidine or bupivacaine alone in spinal anesthesia in patients undergoing elective cesarean section.

Design

The phase 3 clinical trial with a control and parallel group, not blinded and unrandomized on 135 patients in three groups.

Settings and conduct

This evaluation is a clinical trial in phase 3, of pregnant women with indications for elective cesarean section and approved by a gynecologist at Ali ibn Abi Talib Hospital, as the study group. 135 cases with inclusion criteria are selected. Patients fall into three groups with non-randomized allocation without blinding, 45 cases in the first and 45 cases in the second intervention group and 45 in the control group.

Participants/Inclusion and exclusion criteria

Pregnant women with 17 to 45 years of age and class of American Society of Anesthesiologists 1 or 2 will include as study group, also patients with dissatisfaction with study, coagulopathy, increased intracranial pressure, injection site infection, severe intravascular volume decline, severe sensitivity to anesthesia and opioids, pregnancy hypertension, cesarean section requiring blood transfusion, chronic itching, emergency cesarean section because of fetal distress and longer than 1.5 hours of operation excluded from study.

Intervention groups

Before surgery, the first group received 12.5 mg of bupivacaine from Aburaihan pharmaceutical company along with 20 mg of meperidine from caspian pharmaceutical company, and =second group received 12.5 mg of bupivacaine from Aburaihan pharmaceutical company with 2.5 micrograms of sufentanil manufactured by Darou Pakhsh pharmaceutical company was used and in third group only 12.5 mg of bupivacaine was used by Abourihan pharmaceutical company.

Main outcome variables

Severity of pain after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191010045048N1**
Registration date: **2019-10-18, 1398/07/26**
Registration timing: **prospective**

Last update: **2019-10-18, 1398/07/26**
Update count: **0**

Registration date

2019-10-18, 1398/07/26

Registrant information

Name
Neda Norozi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-21, 1398/08/30

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the efficacy of bupivacaine in combination with sufentanil or bupivacaine in combination with meperidine or bupivacaine alone in spinal anesthesia in patients undergoing elective cesarean section

Public title
Comparison the effectiveness of bupivacaine in spinal anesthesia with meperidine and sufentanil in patients undergoing elective cesarean section.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women 17 to 45 years of age Class of American Society of Anesthesiologists 1 as or 2
Exclusion criteria:
Patient dissatisfaction Coagulopathy Increased intracranial pressure Injection site infection Drastic decrease in intravascular volume Severe sensitivity to anesthetics and opioids Pregnancy hypertension Cesarean section requires blood transfusion Chronic itching Emergency cesarean section due to fetal distress Operation length greater than 1.5 hours
Age
From **17 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **135**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zahedan University of Medical Sciences
Street address
9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Approval date
2019-10-04, 1398/07/12
Ethics committee reference number
IR.ZAUMS.REC.1398.248

Health conditions studied

1

Description of health condition studied
Spinal anesthesia
ICD-10 code
O29.5
ICD-10 code description
Other complications of spinal and epidural anesthesia during pregnancy

Primary outcomes

1

Description
Time to reach the T10 anesthesia
Timepoint
During surgery
Method of measurement
Physical examination

2

Description
The time to reach the highest level of Dermatome anesthesia
Timepoint
During surgery
Method of measurement
Physical examination

3

Description
Anesthesia down to T10 level
Timepoint
During surgery
Method of measurement
Physical examination

4

Description

Time to reach full block

Timepoint

After surgery

Method of measurement

Physical examination

5

Description

Motor recovery time

Timepoint

After surgery

Method of measurement

Physical examination

6

Description

Postoperative drowsiness

Timepoint

After surgery

Method of measurement

Physical examination

7

Description

Amount of Diclofenac consumption

Timepoint

After surgery

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 12.5 mg of bupivacaine, manufactured by Aboureihan pharmaceuticals, along with 20 mg of meperidine, manufactured by Caspian pharmaceuticals, were used before surgery.

Category

Treatment - Drugs

2

Description

Intervention group: In this group, 12.5 mg of bupivacaine, manufactured by Aboureihan Pharmaceuticals, along with 2.5 micrograms of sufentanil manufactured by Darou Pakhsh pharmaceutical company, were used before surgery.

Category

Treatment - Drugs

3

Description

Control group: In this group, only 12.5 mg of bupivacaine produced by Aboureihan pharmaceutical company was used before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ibn Abi Talib Hospital

Full name of responsible person

Neda Noruzi

Street address

9816743463, Ali Ibn Abi Talib Hospital, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohammad Reza Shahraki

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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

Zahedan 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
Zahedan University of Medical Sciences

Full name of responsible person
Neda Noruzi

Position
Resident of anesthesiology

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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Position
Anesthesiologist

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Latest degree
Medical doctor

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