

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

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9816743463, Zahedan University of Medical Sciences, Dr. Hesabi Square, Persian Gulf Blvd, Zahedan, Sistan and Baluchestan

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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
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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
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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 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