

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of neonatal complications and Apgar score in mothers under spinal anesthesia for conventional and low doses of bupivacaine and fentanyl

Protocol summary

Study aim

Comparison of neonatal complications and Apgar score in mothers under spinal anesthesia for conventional and low doses of bupivacaine and fentanyl

Design

Clinical trial with control group, parallel groups, double blind, randomized, phase 3, 150 patients

Settings and conduct

A total of 150 pregnant women which referred to Shohadaye Kargar hospital in Yazd included to the study. All patients received one liter of ringer serum before spinal anesthesia. Then, in sitting position in L3-L4 space, spinal anesthesia with needle number 25 performed. In the placebo group, 15 mg bupivacaine injected with 0.5 ml of 1% normal saline, and in the study group, 12.5 mg bupivacaine injected with 0.5% fentanyl 25% intrathecally. For both groups, Neonates' apgar score assessed at specified times and complications such as nausea and chills and the results recorded in a questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All ASA Class 1 female patients underwent non-emergency cesarean section. Exclusion criteria: Eclampsia, preeclampsia, gestational diabetes, hypertension, emergency cesarean section, preeclampsia, acute and chronic fetal distress, under 18 years of age, body mass index more than 40, psychiatric and neurological diseases, drug allergy, addiction to illegal drugs and psychotropics.

Intervention groups

Placebo group: 15 mg bupivacaine 0.5% hyperbaric plus 1 cc normal saline Case group: 12.5 mg bupivacaine 0.5% hyperbaric with 25 µg fentanyl

Main outcome variables

Side effects of medication, neonatal apgar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190817044550N2**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **retrospective**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

Mohammad Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8950 2504

Email address

meditorha@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2018-08-23, 1397/06/01

Trial completion date

2018-08-23, 1397/06/01

Scientific title

Comparison of neonatal complications and Apgar score in mothers under spinal anesthesia for conventional and low doses of bupivacaine and fentanyl

Public title

Comparing the complications and Apgar score in infants

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All ASA Class1 female patients underwent non-emergency cesarean section

Exclusion criteria:

history of chronic disease or mental and physical disability; Under 18 or over 42 years; Being high risk and vulnerable if participate in study based on a gynecologist diagnosis.

Age

From **18 years** old to **42 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **150**

Actual sample size reached: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

We used the permuted block randomization method, and these blocks were randomly designed in Excel software, and then groups equal to the allocation of a as the intervention group and b as the control group were performed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Statistical analyser and outcome assessor were blinded in the study and were unaware of how patients were placed in the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Yazd

Street address

Shohada-e-Gomnam Blvd., Safaeih, Yazd

City

Yazd

Province

Yazd

Postal code

8916871967

Approval date

2017-06-07, 1396/03/17

Ethics committee reference number

IR.IAU.YAZD.REC.1396.4

Health conditions studied

1

Description of health condition studied

Spinal anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Average neonatal apgar score

Timepoint

One minute and five minutes after birth

Method of measurement

Questionnaire adjusted for each patient after anesthesia

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 12.5 mg bupivacaine 0.5% hyperbaric with 25 µg fentanyl

Category

Treatment - Drugs

2

Description

Control group: 15 mg bupivacaine 0.5% hyperbaric with 1 cc normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e-Kargar Hospital

Full name of responsible person

Ahmad Shajari
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Modarres Blvd., Akramieh, Yazd
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sponsor Vice-chancellor of research, Islamic Azad University, Faculty of Medicine, Branch of Yazd
Full name of responsible person
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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

Sponsor Vice-chancellor of research, Islamic Azad University, Faculty of Medicine, Branch of Yazd

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
Islamic Azad University
Full name of responsible person

Masoud Khoshbin
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Assistant professor
Latest degree
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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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