

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Oct 2026

Comparison of the effect of 5 and 10 µg bolus doses of intravenous norepinephrine on the prevention of hypotension after spinal anesthesia with 0.5% bupivacaine in cesarean section: a double-blind randomized clinical trial

Protocol summary

Study aim

Determining and comparing the effect of 5 and 10 µg bolus doses of intravenous norepinephrine on the prevention of hypotension after spinal anesthesia with 0.5% bupivacaine in cesarean section: a double-blind randomized clinical trial

Design

This clinical trial with a control group with parallel, double-blind, randomized, phase 2-3 groups was performed on 126 pregnant patients aged 18-46 years who were candidates for cesarean section and randomization block was used for randomization.

Settings and conduct

Immediately after spinal anesthesia, 42 patients received 5 micrograms of norepinephrine, 42 patients received 10 micrograms of norepinephrine, and 42 patients received 1 ml of normal saline intravenously, then systolic and diastolic blood pressure, mean arterial pressure and heart rate are measured and recorded every two minutes to 10 minutes, then every 5 minutes to 15 minutes and then every 10 minutes until the end of the operation.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Satisfaction to participate in the project; Pregnant patients 18 to 46 years old; Term pregnancy and a candidate for cesarean section under spinal anesthesia. Exclusion Criteria: No spinal anesthesia and induce general anesthesia; Existence of lung and heart diseases and fever; Emergency cesarean section; Eclampsia and preeclampsia; Multiple pregnancies; Contraindications to spinal anesthesia; History of taking ergotamine and an initial systolic pressure of less than 90 mmHg.

Intervention groups

Immediately after spinal anesthesia, patients in group A, 5 microgram of norepinephrine (volume of 1 ml) and in group B, 10 micrograms of norepinephrine (volume of 1

ml) and in group C 1 ml of normal saline as a control group, injected intravenously.

Main outcome variables

Hypotension

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N24**

Registration date: **2020-12-26, 1399/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-26, 1399/10/06**

Update count: **0**

Registration date

2020-12-26, 1399/10/06

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 5 and 10 µg bolus doses of intravenous norepinephrine on the prevention of hypotension after spinal anesthesia with 0.5% bupivacaine in cesarean section: a double-blind randomized clinical trial

Public title

The effect of Norepinephrine on the prevention of post spinal hypotension

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Satisfaction to participate in the project Pregnant women aged 18 to 46 and term pregnancy Candidate for cesarean section under spinal anesthesia

Exclusion criteria:

Patients who have failed spinal anesthesia and undergo general anesthesia Lung disease, heart disease, fever, hypertension, diabetes and cardiac arrhythmia Emergency cesarean section due to meconium and fetal distress preeclampsia and eclampsia Multiple pregnancies Contraindications to spinal anesthesia (high ICP, hypovolemia, anemia, coagulation disorders, etc.) History of taking ergotamine Initial systolic pressure less than 90 mmHg

Age

From **18 years** old to **46 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **126**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, Block Randomization method is used as 6 blocks for randomization. In this way, we put 6 pieces of paper with the letter A and 6 pieces of paper with the letter B and 6 pieces of paper with the letter C in a bag and mix them, then for each patient that enters the study, one of the papers is taken out randomly and will be assigned to one of the three groups: A (norepinephrine 5 micrograms), B (norepinephrine 10 micrograms) and group C (normal saline), depending on whether the drawn sheet is either A, B or C. Then, for

the next series of patients, the papers are returned to the bag and the same process is repeated until the end of the sample volume.

Blinding (investigator's opinion)

Double blinded

Blinding description

Immediately after spinal anesthesia in group A, 5 micrograms of intravenous norepinephrine (1 ml), in group B, 10 micrograms of intravenous norepinephrine (1 ml) and in group C, 1 ml normal saline as a control group In similar syringes , which are pre-specified by the anesthesia nurse according to the list, are prepared and injected intravenously.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

Street address

Mahdieh Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2020-07-11, 1399/04/21

Ethics committee reference number

IR.UMSHA.REC.1399.374

Health conditions studied**1****Description of health condition studied**

Spinal anesthesia in cesarean section

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Blood pressure

Timepoint

Every two minutes to 10 minutes, then every 5 minutes to 15 minutes, and every 10 minutes until the end of the

surgery
Method of measurement
Automatic non-invasive blood pressure device

Secondary outcomes

1

Description

Heart Rate

Timepoint

Every two minutes to 10 minutes, then every 5 minutes to 15 minutes, and every 10 minutes until the end of the surgery

Method of measurement

pulse oximetry

2

Description

Nausea and Vomiting

Timepoint

During and after surgery

Method of measurement

Observation

3

Description

New born Apgar

Timepoint

1&5 minutes after delivery

Method of measurement

Apgar Score

4

Description

The amount of ephedrine have been consumed

Timepoint

During surgery

Method of measurement

mg

5

Description

The amount of atropine have been consumed

Timepoint

During surgery

Method of measurement

mg

Intervention groups

1

Description

Intervention group1: Immediately after spinal anesthesia in group A, 5 micrograms of intravenous norepinephrine (with a volume of one ml) of 0.1% norepinephrine ampoule made by Normon Spain (importer of Tadbir

Kalay Jam) is injected intravenously. Then systolic, diastolic blood pressure, mean arterial pressure and heart rate of the patient at specific intervals are measured and recorded.

Category

Prevention

2

Description

Intervention group 2: Immediately after spinal anesthesia in group B, 10 micrograms of intravenous norepinephrine (with a volume of one ml) of 0.1% norepinephrine ampoule made by Normon Spain (importer of Tadbir Kalay Jam) is injected intravenously. Then systolic, diastolic blood pressure, mean arterial pressure and heart rate of the patient at specific intervals are measured and recorded.

Category

Prevention

3

Description

Control group: Immediately after spinal anesthesia in group C, one milliliter of normal saline is injected intravenously as a placebo. Then systolic, diastolic blood pressure, mean arterial pressure and heart rate of the patient at specific intervals are measured and recorded.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Nahid Manouchehrian

Position

Associate professor of Hamadan University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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inquiries

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Latest degree

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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