

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of norepinephrine with phenylephrine in the prevention and treatment of hypotension in cesarean section undergoing spinal anesthesia

Protocol summary

Study aim

Comparison of norepinephrine with phenylephrine in the prevention and treatment of hypotension in cesarean section undergoing spinal anesthesia

Design

Clinical trial, with parallel groups, double-blind, randomized, phase 3 on 40 patients.

Settings and conduct

In this randomized double-blind clinical trial performed on 40 pregnant women undergoing spinal anesthesia in Mahzad hospital in Urmia, patients in two groups of 20 will randomly receive 5 micrograms of phenylephrine or 5 micrograms of norepinephrine. Patients and statistical analyzers will be unaware of group assignments.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Satisfaction to participate in the study, age between 20 to 45 years, lack of sensitivity to phenylephrine and norepinephrine - Exclusion criteria: having liver, kidney and heart diseases- sensitivity to anesthetics

Intervention groups

First intervention group: 5 micrograms phenylephrine-
Second intervention group: 5 micrograms norepinephrine

Main outcome variables

Systolic blood pressure, diastolic blood pressure, nausea, vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201207049639N8**

Registration date: **2022-03-31, 1401/01/11**

Registration timing: **prospective**

Last update: **2022-03-31, 1401/01/11**

Update count: **0**

Registration date

2022-03-31, 1401/01/11

Registrant information

Name

Hadi Houshyar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

hooshyar.h@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of norepinephrine with phenylephrine in the prevention and treatment of hypotension in cesarean section undergoing spinal anesthesia

Public title

Effect of norepinephrine with phenylephrine in the prevention of hypotension undergoing spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study Age between 20 to 45 years Lack of sensitivity to norepinephrine and phenylephrine

Exclusion criteria:

Having liver, kidney and heart disease Sensitivity to anesthetics

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects; it means we will have 10 blocks (Totally 40 patients). Then, within each block, subjects will be randomly assigned to norepinephrine or phenylephrine group . Random assignment will be done using a random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were unaware of their allocation into the intervention groups and the statistical analyzer received the data as codes, not the actual grouping. Patients remain unaware of being in intervention groups because after spinal anesthesia patients are prescribed sedatives and drugs are administered intra serum and the patient is unable to distinguish the type of drug because both are stored in brown glass. The statistical analyzer also received the data in codes A and B, not the norepinephrine and phenylephrine groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Resalat Street, Jahad Ave., Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2021-12-01, 1400/09/10

Ethics committee reference number

IR.UMSU.REC.1400.376

Health conditions studied

1

Description of health condition studied

Hypotension

ICD-10 code

I95

ICD-10 code description

Hypotension

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before intervention, 5, 10, 15, 20, 25 and 30 minutes after intervention

Method of measurement

Blood pressure monitor

2

Description

Diastolic blood pressure

Timepoint

Before intervention, 5, 10, 15, 20, 25 and 30 minutes after intervention

Method of measurement

Blood pressure monitor

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

It is recorded up to 30 minutes after the intervention if observed

Method of measurement

Observation

Intervention groups

1

Description

Intervention group 1: In all patients, 10 mg (2 cc) of bupivacaine 0.5% (Produced by Caspian company) is injected intrathecally, and after the patient is in a supine position, systolic and diastolic blood pressure are measured and recorded every 5 minutes. In cases where the systolic blood pressure drops more than 20% of the initial value, 50 micrograms of phenylephrine (Produced by Caspian company) will be injected intravenously.

Category

Treatment - Drugs

2

Description

Intervention group 2: In all patients, 10 mg (2 cc) of bupivacaine 0.5% (Produced by Caspian company) is injected intrathecally, and after the patient is in a supine position, systolic and diastolic blood pressure are measured and recorded every 5 minutes. In cases where the systolic blood pressure drops more than 20% of the initial value, 5 micrograms of norepinephrine (Produced by Caspian company) will be injected intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahzad Women's Medical Center

Full name of responsible person

Dr. Hadi Hooshyar

Street address

Mahzad Women's Medical Center; Hasani street, Urmia, Iran.

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hooshyar.h@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

Street address

Urmia University of Medical Sciences; Resalat street; Jahad Blvd; Urmia; Iran.

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hadi Hooshyar

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Shahid Motahhari Hospital; Kashani street; Urmia; Iran.

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Person responsible for scientific

inquiries

Contact

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Oroumia University of Medical Sciences

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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