

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anaesthesia for caesarean section

Protocol summary

Study aim

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anaesthesia for caesarean section.

Design

Women undergoing caesarean section under spinal anaesthesia 18 to 35 years

Settings and conduct

This double-blind clinical trial study will be performed on 100 patients undergoing caesarean section in two groups at Mousavi Hospital in Zanjan. Random allocation of samples is done by block method and using statistical software. A digital sphygmomanometer will be used to measure blood pressure and heart rate. Completion of questionnaires and recording of variables will be done by the research team during the operation and at specified times.

Participants/Inclusion and exclusion criteria

Entry requirements: Patients who are candidates for elective caesarean section, full-term pregnancy (37 full weeks) and singleton, patients with American Society of Anesthesiologists (ASA) 1 and 2, no underlying diseases, no drug and alcohol abuse
Exit conditions: Congenital malformations of the infant, patients who have had a previous caesarean section performed midline, patients who, for whatever reason, the time between spinal anaesthesia and the discharge of the baby is longer than usual (20 Minutes), patients who have failed during spinal anaesthesia

Intervention groups

Intervention group: Pregnant women with term pregnancies and aged 18 to 35 years who receive norepinephrine infusion (4µg / min) immediately after spinal anaesthesia until the end of caesarean section
Control group: Pregnant women with term gestation and aged 18 to 35 years who receive phenylephrine infusion (4 µg / min) immediately after spinal anaesthesia until

the end of caesarean section

Main outcome variables

Systolic blood pressure; Diastolic blood pressure; Moderate blood pressure; heart rate; Arterial umbilical cord blood gases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210502051160N1**
Registration date: **2021-07-11, 1400/04/20**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-11, 1400/04/20**

Update count: **0**

Registration date

2021-07-11, 1400/04/20

Registrant information

Name

mitra hojatansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3341 5118

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mitraansari@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-10, 1400/03/20

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anaesthesia for caesarean section

Public title

Comparison of the effect of norepinephrine and phenylephrine infusion for the prevention of hypotension during spinal anaesthesia for caesarean section

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients candidate for cesarean section selectively Term pregnancy (37 full weeks) and singleton Patients with anesthesia class (ASA) 1 and 2 No abuse of drugs, drugs and alcohol

Exclusion criteria:

Congenital malformations of the neonate Patients in a position suspected of having a dead fetus Patients whose previous cesarean section is midline

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the restricted randomization method we use the block randomization type. Blocking is used to balance the number of samples assigned to each of the study groups. This feature helps the researcher to equate the number of samples assigned to each of the study groups whenever intermediate analyzes are needed during sampling. The size of all the blocks is equal and in this two-group experiment we will have 6 blocks (including 3 people in the intervention group and 3 people in the control group).software allocation Random is used for randomization. In addition to simple randomization, these softwares are able to generate random sequence by blocking method. For concealment, we use concealment allocation, which is the method used to execute a random sequence on the study participants, so that the assigned group is not known before the individual is assigned. Using opaque envelopes with random sequences (envelopes opaque,

sealed, numbered sequentially), each of the random sequences created is written on a card and the cards are placed inside the envelopes in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the letter envelopes are glued and placed in a box, respectively. At the time of arrival of eligible pregnant mothers, according to the order of inclusion in the study, one of the envelopes is opened and the assigned group of the pregnant mother is revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug will be inserted anonymously into the infusion syringe

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Zanjan University of Medical Sciences

Street address

Vice-Chancellor for Research and Technology, 3th Floor, 2th Bldg., Zanjan University of Medical Sciences, Azadi Blvd. Zanjan, IRAN.

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.ZUMS.REC.1400.047

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

hypotension during spinal anaesthesia

ICD-10 code

I95.81

ICD-10 code description

Postprocedural hypotension

Primary outcomes

1

Description

blood pressure

Timepoint

per one minute

Method of measurement

electronical pressure gauge

Secondary outcomes

empty

Intervention groups

1

Description

Patients in intervention group 1: After spinal anesthesia for cesarean section in pregnant women, intravenous infusion of norepinephrine 5 micrograms per minute up to a maximum of 60 ml per minute is started. Intervention group:

Category

Prevention

2

Description

Patients in intervention group 2: After spinal anesthesia for cesarean section in pregnant women, intravenous infusion of phenylephrine half a mg per minute to a maximum of 60 ml per minute is started. Intervention group:

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

saeid jalili

Street address

Ayatollah Mousavi Educational and Medical Center, Gavazang, Zanjan, IRAN.

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Mousavihospital@zums.ac.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Shoghli

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Saeed Jalili

Position

Assistant professor

Latest degree

Specialist

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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Not applicable

Title and more details about the data/document

There is no more information.

When the data will become available and for how long

There is no more information.

To whom data/document is available

There is no more information.

Under which criteria data/document could be used

There is no more information.

From where data/document is obtainable

There is no more information.

What processes are involved for a request to access data/document

There is no more information

Comments