

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the prophylactic infusion effect of Phenylephrine on hypotension in cesarean section under spinal anesthesia

Protocol summary

Study aim

Evaluation of the prophylactic infusion effect of phenylephrine on hypotension in cesarean section under spinal anesthesia

Design

In this double-blind clinical trial study, pregnant women candidates for cesarean section under spinal anesthesia were included. The patients were randomly allocated into intervention or control groups based on generated computer numbers.

Settings and conduct

This study was conducted on pregnant women undergoing cesarean section under spinal anesthesia admitted to Urmia Shahid Motahari. This study was a double-blind study and both of the patients and the researcher were blind to the belonging of the patients to the intervention or control group.

Participants/Inclusion and exclusion criteria

In this double-blind clinical trial study, pregnant women candidates for cesarean section under spinal anesthesia and ASA I and ASA II were included. Patients with classic hypertension or gestational hypertension, patients with pulmonary, cardiovascular, and cerebrovascular diseases, and also fetal abnormalities were excluded.

Intervention groups

The participants were randomly divided into two groups based on generated computer numbers. Patients in the intervention group received 100 micrograms per hour of Phenylephrine infusion. Patients in the control group received the same amount of normal saline.

Main outcome variables

Hypotension which was considered as a decrease in systolic blood pressure by 80% of the baseline;
Hypertension was considered as an increase in systolic blood pressure above 120% of the baseline.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201207049639N1**
Registration date: **2020-12-20, 1399/09/30**
Registration timing: **retrospective**

Last update: **2020-12-20, 1399/09/30**

Update count: **0**

Registration date

2020-12-20, 1399/09/30

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

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

2019-03-21, 1398/01/01

Actual recruitment end date

2020-03-19, 1398/12/29

Trial completion date

2020-03-19, 1398/12/29

Scientific title

Evaluation of the prophylactic infusion effect of Phenylephrine on hypotension in cesarean section under spinal anesthesia

Public title

Evaluation of the Phenylephrine effect on hypotension in cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Pregnant women candidates for cesarean section under spinal anesthesia American Society of Anesthesiologists classification system I and II (ASA II and ASA II)

Exclusion criteria:

Patients with classical hypertension Gestational hypertension Patients with pulmonary and cardiovascular diseases Patients with cerebrovascular disease Fetal abnormality

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into intervention and control groups using random allocation computer software. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients allocated into two groups according computer generated numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was a double-blind clinical trial. participants and researcher were unaware about the patient belonged to the intervention or control groups. The drug were injected by an anesthesia technician (other than the researcher) who was unaware of the content of the study.

Placebo

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

2019-01-16, 1397/10/26

Ethics committee reference number

IR.UMSU.REC.1397.408

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

Hypotension

ICD-10 code

I95

ICD-10 code description

Hypotension

Primary outcomes**1****Description**

Hypotension, which was considered as a decrease in systolic blood pressure by 80% of the baseline.

Timepoint

Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.

Method of measurement

Blood pressure monitoring device

Secondary outcomes**1****Description**

Hypertension was considered as an increase in systolic blood pressure above 120% of the baseline

Timepoint

Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.

Method of measurement

Blood pressure monitoring device

2**Description**

Nausea

Timepoint

Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.

Method of measurement

Interview

3

Description

Vomiting

Timepoint

Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.

Method of measurement

Interview

4

Description

Bradycardia (decrease in heart rate to less than 60 beats per minute)

Timepoint

Before the intervention and in 5, 15, 25, 35 and 45 minutes after the intervention.

Method of measurement

Heart rate monitoring device.

Intervention groups

1

Description

Intervention group: patients in the intervention group received 100 micrograms per hour of Phenylephrine infusion

Category

Treatment - Drugs

2

Description

Control group: patients in the control group received 100 micrograms of normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Motahari Hospital

Full name of responsible person

Dr. Hadi Hooshyar

Street address

Shahid Motahhari hospital; Kashani street, Urmia, Iran.

City

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Postal code

5714783734

Phone

+98 44 3198 8293

Email

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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mohebbi.i@umsu.ac.ir

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

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Shahid Motahhari Hospital; Kashani street; Urmia;

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The results of the study will be published as an article.

When the data will become available and for how long

After publishing the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

As published article

From where data/document is obtainable

Corresponding author

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

By email address of corresponding author

Comments