Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effect of norepinephrine and phenylephrine on maternal hemodynamic changes after spinal anesthesia in cesarean section

Protocol summary

Study aim
Comparison of the effect of norepinephrine and phenylephrine on maternal hemodynamic changes after spinal anesthesia in cesarean section

Design
The clinical trial was randomized with parallel, single-blind, phase three, groups in which 52 patients were randomly assigned to two groups of 26 patients with a size of 4 blocks.

Settings and conduct
Pregnant women aged 18-35 years are candidates for elective cesarean delivery referred to Ayatollah Rouhani Educational and Medical Center of the study community. Patients will be randomly divided into intervention group 1: after spinal anesthesia injection of prophylaxis bolus 10 micrograms norepinephrine and group 2 intervention: after spinal anesthesia injection of prophylaxis bolus 100 micrograms phenylephrine. Syringes containing norepinephrine and phenylephrine Put one shape, one size and correct inside the cans and then write a 3-digit code on each can. After the patient enters the study, one of these cans is assigned to the patient and the code is written on the can on the patient's file (study checklist). Unlock the codes will be done after the study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria:18 to 35 years pregnant women, Elective cesarean Section, American Society of Anesthesiologists Classification (ASA) I,II Inclusion Criteria: ASA Class>3, Bradycardia, Hypertension, Use of anti hypertensive drugs, Operation longer than 3 hours

Intervention groups
Intervention group 1: After spinal anesthesia, prophylaxis injection of 10 micrograms of norepinephrine
Intervention group 2: After spinal anesthesia, prophylaxis injection of 100 micrograms phenylephrine

Main outcome variables
Blood pressure, Heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20101213005381N15**
Registration date: **2022-05-29, 1401/03/08**
Registration timing: **prospective**

Last update: **2022-05-29, 1401/03/08**
Update count: **0**

Registration date
2022-05-29, 1401/03/08

Registrant information

Name
Nadia Banihashem

Name of organization / entity
Babol University Of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 22 38296

Email address
nbanihashem@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-31, 1401/03/10

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of norepinephrine and phenylephrine on maternal hemodynamic changes after spinal anesthesia in cesarean section

Public title
The effect of norepinephrine and phenylephrine on maternal hemodynamic changes

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
18 to 35 years pregnant women Elective cesarean delivery American Society of Anesthesiologists Classification (ASA) 1 &2

Exclusion criteria:
American Society of Anesthesiologists Classification (ASA) > 3 Bradycardia Hypertension Use of anti hypertensive drugs Operation longer than 3 hours

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

Gender
Female

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using block blocks of block size 4. Thus, 4 blocks consist of random combinations of compounds 2 to A (phenylephrine) and 2 to B (norepinephrine). Random sequencing of blocks will be done by a statistician.

Blinding (investigator's opinion)
Single blinded

Blinding description
The blindness of the study is that patients are unaware of the medication regimen, but the anesthesiologist, the patient evaluator (anesthesia assistant) is aware of the regimen.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Babol University of Medical Siences

Street address
Babol University of Medical Sciences, Gangafrooz Street, Daneshgah Square,

City
Babol

Province
Mazandaran

Postal code
471764136

Approval date
2022-04-25, 1401/02/05

Ethics committee reference number
IR.MUBABOL.REC.1401.026

Health conditions studied

1

Description of health condition studied
Cesarean Section

ICD-10 code
O74

ICD-10 code description
Complications of anesthesia during labor and delivery

Primary outcomes

1

Description
Percentage of people with hypertension

Timepoint
Before spinal anesthesia once and then after spinal anesthesia once every 3 minutes until the baby leaves and then twice 10 minutes after delivery.

Method of measurement
Monitoring of blood pressure, mm Hg

2

Description
Number of Heart rate

Timepoint
Before spinal anesthesia once and then after spinal anesthesia once every 3 minutes until the baby leaves and then twice 10 minutes after delivery.

Method of measurement
Number per minute using pulse oximeter (Sazgan Gostar Company)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After spinal anesthesia, prophylaxis injection of 10 micrograms of norepinephrine
Intervention group

Category
Prevention

2

Description
Intervention group: After spinal anesthesia, prophylaxis injection of 100 micrograms phenylephrine

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Rouhani Hospital

Full name of responsible person
Nadia Banihashem

Street address
Ganjafrooz Avenue, Daneshgah Square, Ruhani Hospital

City
Babol

Province
Mazandaran

Postal code
47176-47745

Phone
+98 11 3233 8301

Email
n.banihashem@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Reza Ghadimi

Street address
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City
Babol

Province
Mazandaran

Postal code
47176-41367

Phone
+98 11 3219 7667

Email
rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Nadia Banihashem

Position
Associated Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City
Babol

Province
Mazandaran

Postal code
47176-41367

Phone
+98 11 3233 8301

Email
nbanihashem@mubabol.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Nadia Banihashem

Position
Associated Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City
Babol

Province
Mazandaran
Postal code
47176-41367
Phone
009891132338301
Email
nbanihashem@mubabol.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Nadia Banihashem
Position
Associated Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
nbanihashem@mubabol.ac.ir

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
There is still no plan for its publish
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