# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

06 Nov 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