

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Evaluation of the comparative effect of hemodynamic changes due to prophylactic Prescription of phenylephrine in three forms: bolus, subcutaneous and infusion in mothers with selective cesarean section under spinal anesthesia with marcaine

#### Protocol summary

##### Study aim

Determining the comparative effect of hemodynamic changes due to prophylactic administration of phenylephrine in three forms of bolus, subcutaneous and infusion in mothers with elective cesarean section under spinal anesthesia with marcaine

##### Design

A clinical trial study on three intervention groups receiving phenylephrine in the form of bolus, subcutaneous and infusion with the control group. There are 30 people for each group. The study is a blind and randomized block study.

##### Settings and conduct

Background: Anesthesia Location: Operating room of Ilam city hospitals Methods: Evaluation of hemodynamic changes before, during and after prophylactic phenylephrine injection and also in the control group method : Subcutaneous: 5 to 10 minutes before anesthesia, 5 mg phenylephrine at the site of deltoid Infusion: 1 to 2 minutes before anesthesia  $\mu\text{g} / \text{kg} / \text{min}$  0.15 phenylephrine for 30 minutes Bolus: 1 to 2 minutes before anesthesia  $1/5 \mu\text{g} / \text{kg}$  Control group: no injection and in cases with pressure drop phenylephrine bolus and stat How to blind: The researcher does not know about the intervention performed for each case when recording data

##### Participants/Inclusion and exclusion criteria

Inclusion: Single term pregnant women 18 to 35 years old at the risk of anesthesia I and II of the American Anesthesia Association who are candidates for elective cesarean section Exclusion: Women with a history of high blood pressure (BP> 140/90), diabetes, cardiovascular and cerebral disease, known fetal abnormalities, any contraindications to spinal anesthesia, and mothers at the beginning of the labor phase

##### Intervention groups

Bolus, infusion, subcutaneous and control in 3 intervention groups, prophylactic administration is performed, but not in the control group

##### Main outcome variables

Blood pressure ; Heart beat ; Apgar score; Arterial blood test results including PH, Paco<sub>2</sub>, Base excess and HCO<sub>3</sub>

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200725048206N1**

Registration date: **2020-08-20, 1399/05/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-08-20, 1399/05/30**

Update count: **0**

##### Registration date

2020-08-20, 1399/05/30

##### Registrant information

##### Name

Majid Aftabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 84 3222 1999

##### Email address

majidaftabi73@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-31, 1399/05/10  
**Expected recruitment end date**  
2020-08-22, 1399/06/01  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Evaluation of the comparative effect of hemodynamic changes due to prophylactic Prescription of phenylephrine in three forms: bolus, subcutaneous and infusion in mothers with selective cesarean section under spinal anesthesia with marcaine

**Public title**  
Evaluation of the effect of phenylephrine in cesarean section

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Pregnant women Term Single pregnancy Elective cesarean section candidate  
**Exclusion criteria:**  
History of hypertension (BP> 140/90 Diabetes Cardiovascular and cerebral disease Recognized fetal anomaly Any contraindication to spinal anesthesia Mothers who are at the beginning of the labor phase

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

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Investigator

**Sample size**  
Target sample size: **120**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
After completing the baseline assessment, patients were divided into three intervention groups and one control group. Randomization was performed using the block method (with block size of 4 or 6 and allocation ratio of 1: 1). Block randomization is used to reduce bias and achieve equilibrium in allocating participants to the study groups. Random allocation concealment was performed using opaque sealed envelopes with random sequences. Random allocation sequence is done using a computer-generated Kendall and Smith random number table. These tables have random numbers in both row and column directions, usually up to 99 rows and columns, and row and column digits. The cells are placed in five-digit blocks next to each other and separately to facilitate its use. This step is performed by a statistician who is not part of the research team. The random allocation sequence was hidden in closed opaque

envelopes so that participants were assigned to 4 groups.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
The anesthesiologist and other members of the treatment staff and participants in the study are informed but the researcher is not As follows: Participants will be notified upon consent According to the decision of the anesthesiologist, one of the intervention methods is selected and after the prescription, the researcher, who is not aware of the prescription method, starts recording the data.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**  
Ethics Committee of Ilam University of Medical Sciences

**Street address**  
Ilam University of Medical Sciences Campus , Banganjab, Research Blvd. , Ilam

**City**  
Ilam

**Province**  
Ilam

**Postal code**  
6939177143

**Approval date**  
2020-07-14, 1399/04/24

**Ethics committee reference number**  
IR.MEDILAM.REC.1399.140

**Health conditions studied**

**1**

**Description of health condition studied**  
Hemodynamics of pregnant women under spinal anesthesia

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

**1**

**Description**  
Blood pressure

**Timepoint**

Base and minutes 5 and 15 and 30 and 60 and 90 and 120

**Method of measurement**

Cardiac monitor machine and blood pressure meter

**2**

**Description**

Heart rate

**Timepoint**

Base and minutes 5 and 15 and 30 and 60 and 90 and 120

**Method of measurement**

Cardiac monitor machine and pulse oximeter

**3**

**Description**

Apgar score

**Timepoint**

Minutes 1 and 5

**Method of measurement**

Physical examination

**4**

**Description**

Umbilical cord blood Paco2 test

**Timepoint**

After birth

**Method of measurement**

Laboratory instruments

**5**

**Description**

Umbilical cord blood HCO3 test

**Timepoint**

After birth

**Method of measurement**

Laboratory instruments

**6**

**Description**

Umbilical cord blood pH test

**Timepoint**

After birth

**Method of measurement**

Laboratory instruments

**7**

**Description**

Umbilical cord blood Base excess test

**Timepoint**

After birth

**Method of measurement**

Laboratory instruments

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Intervention group 1: Bolus method: For patients who are going to receive bolus prophylactic phenylephrine (Beacon Pharmaceuticals Ltd) , 1.5 µg / kg of phenylephrine is injected 1 to 2 minutes before anesthesia. If systolic blood pressure drops by 20% of basal systolic blood pressure, 50 µg of intravenous phenylephrine is given intermittently. In cases where the heart rate is less than 50 beats per minute, atropine (Darou Pakhsh Co) 0.5 mg is prescribed.

**Category**

Prevention

**2**

**Description**

Intervention group 2: Infusion method: For patients who are going to receive infusion prophylactic phenylephrine (Beacon Pharmaceuticals Ltd) , 0.15 g / kg / min phenylephrine is injected intravenously for 30 minutes 1 to 2 minutes before anesthesia . If systolic blood pressure drops by 20% of basal systolic blood pressure, 50 g of intravenous phenylephrine is given intermittently. In cases where the heart rate is less than 50 beats per minute, atropine (Darou Pakhsh Co) 0.5 mg is prescribed. In the infusion group, the drug is discontinued if the systolic blood pressure increases by more than 20% of baseline.

**Category**

Prevention

**3**

**Description**

Intervention group 3: subcutaneous: For patients who are supposed to receive subcutaneous prophylactic phenylephrine (Beacon Pharmaceuticals Ltd) , 5 to 10 minutes before anesthesia, 5 mg of phenylephrine is injected into the deltoid site. In case of systolic blood pressure drop by 20% the base of systolic blood pressure is given alternately 50 µg of intravenous phenylephrine. In cases where the heart rate is less than 50 beats per minute, atropine (Darou Pakhsh Co) 0.5 mg is prescribed.

**Category**

Prevention

**4**

**Description**

Control group: In patients in the control group who do not receive phenylephrine (Beacon Pharmaceuticals Ltd), in case of systolic blood pressure drop of less than 20% of baseline or less than 100 mm Hg, they receive µg/kg 1/5 of phenylephrine in bolus and STAT, and in case of drop again the dose is repeated

**Category**

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Ayatollah Taleghani Hospital of Ilam

**Full name of responsible person**

Dr Tayyebe rashidian

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Shahid Beheshti Blvd., Reporter Blvd.

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Ilam University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Karimian

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Research Blvd.,Bangangab

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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**

Ilam 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**

Ilam University of Medical Sciences

**Full name of responsible person**

Majid Aftabi

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

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## Person responsible for scientific inquiries

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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