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 µg / kg / min0.15 phenylephrine for 30 minutes Bolus: 1 to 2 minutes before anesthesia 1/5 µg / 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, Paco2, Base excess and HCO3

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

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Iran (Islamic Republic of)

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+98 84 3222 1999

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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 µ g / 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
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Sponsors / Funding sources

1

Sponsor

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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

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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