

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of spinal anesthesia with Low & Conventional Bupivacaine dose On blood Pressure changes in severe Preeclamptic patients Candidate for cesarean section

Protocol summary

Summary

Objective: Comparison of Low & Conventional Bupivacaine dose on blood Pressure changes in severe Preeclamptic patients Candidate for cesarean section under spinal anesthesia. Design and setting: a randomized block design, clinical trial study, double-blind, single center, clinical trial phase 2, 60 samples Inclusion criteria: Patients with severe preeclampsia and candidate for caesarian section under spinal anesthesia; ASA I or II; Platelets greater than or equal to 100000. Exclusion criteria: Failure in spinal anesthesia; Heart failure; Active bleeding; History of renal or hepatic failure. Interventions: Group 1 receive lower dose of Bupivacaine 0.5 % (7.5 mg), and group 2 receive conventional dose of Bupivacaine 0.5 % (12.5 mg). Main outcome measures: Vital signs, systolic and diastolic blood pressure and Mean arterial pressure check, before and after spinal anesthesia and every 5 minutes until end of operation. Apgar scores check at first and 5th minutes after birth.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091714056N9**
Registration date: **2016-09-27, 1395/07/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-27, 1395/07/06

Registrant information

Name

Hesameddin Modir

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3313 9680

Email address

he_modir@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date

2016-05-23, 1395/03/03

Expected recruitment end date

2016-10-24, 1395/08/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of spinal anesthesia with Low & Conventional Bupivacaine dose On blood Pressure changes in severe Preeclamptic patients Candidate for cesarean section

Public title

Comparison of Low & Conventional Bupivacaine dose On blood Pressure changes in severe Preeclamptic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with severe preeclampsia and candidate for caesarian section under spinal anesthesia; ASA I or II; Platelet greater than or equal to 100000; No

History of sensitivity to the local anesthetic drug.
Exclusion criteria: Failure in spinal anesthesia;
Uncooperative patient in determining the sensory level;
Heart failure; Active bleeding; History of renal or hepatic failure; Intracranial hemorrhage or stroke; Neurologic diseases; Psychiatric disorders(Schizophrenia; schizoaffective disorder; schizophreniform disorder; Bipolar disorder); ASA greater than or equal 3

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht, Arak, Iran.

City

Arak

Postal code**Approval date**

2016-05-23, 1395/03/03

Ethics committee reference number

IR.ARAKMU.REC.1395.91

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

severe preeclampsia

ICD-10 code

O14.1

ICD-10 code description

Severe pre-eclampsia

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

Systolic blood pressure

Timepoint

before and after spinal anesthesia and every 5 minutes until end of operation

Method of measurement

sphygmomanometer

2**Description**

Diastolic blood pressure

Timepoint

before and after spinal anesthesia and every 5 minutes until end of operation

Method of measurement

sphygmomanometer

3**Description**

Mean arterial pressure

Timepoint

before and after spinal anesthesia and every 5 minutes until end of operation

Method of measurement

sphygmomanometer

4**Description**

Pulse rate

Timepoint

before and after spinal anesthesia and every 5 minutes until end of operation

Method of measurement

pulse rate per minute

5**Description**

Oxygen saturation

Timepoint

before and after spinal anesthesia and every 5 minutes until end of operation

Method of measurement

Pulse oximeter

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

Apgar score

Timepoint

at 1 and 5 minutes after birth

Method of measurement

Questionare

Intervention groups

1

Description

Intervention: Group 1 receive lower dose of Bupivacaine 0.5 % (7.5 mg).

Category

Treatment - Drugs

2

Description

Control: Group 2 receive conventional dose of Bupivacaine 0.5 % (12.5 mg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Hesameddin Modir

Street address

Taleghani hospital, Emam Khomeini street, Arak, Iran

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

DR Mohammad Rafeie

Street address

Arak University of Medical Sciences, Basij Square, Sardash, Arak, Iran

City

Arak

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak University of Medical Sciences, Vice Chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Hesameddin Modir

Position

Anesthesiologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty