Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of headache prevalence and intensity following administration of ephedrine and phenylephrine in cesarean section under spinal anesthesia

Protocol summary

Summary

This investigation is designed as a unicenter, phase 2-3 clinical trial. 105 single fetus pregnant women who are candidate for elective cesarean, 18 to 40 years old, ASA class I-II with systolic blood pressure 120-140 mmhg will enter the trial. In all patients anesthetic approach is spinal block with bupivacaine 0.5%. In patients with hypotention that need to treat with vasopressor, randomly phenylephrine or ephedrine will prescribed. Changes of blood pressure, heart rate, type and amount of vasopressor and severity of headache (visual analogue scale) is measured and recorded by anesthesia nurse who will blind with the type of the group and vasopressor.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509042946N7**
Registration date: **2016-12-07, 1395/09/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-07, 1395/09/17

Registrant information

Name

Mitra Yari

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

myari@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-08-21, 1395/05/31

Expected recruitment end date

2017-02-18, 1395/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of headache prevalence and intensity following administration of ephedrine and phenylephrine in cesarean section under spinal anesthesia

Public title

comparison of headache accurance and severity after use of phenylephtine and ephedrine for treatment of hypotention during cesarian delivery under spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women aged 18 to 40 years; ASA class I_II; systolic blood pressure 120-140 mmhg; body mass index 18.5_25 and normal single fetus pregnancy. Exclusion criteria: History of migraine; psychiatric disorders; any medication except pregnancy supplements; presence of headache in admission time to operation room; eclampsia; preeclampsia; hypertention; diabetes mellitus and cardiovascular disease.

Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **105**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Drug prepration will done by an anesthetic nurse. Drug prescription will done by second and evaluation of accurance and severity of headache will done by third nurse. All of nurses and patientswill blinded with type of vasopressor. Randomization will done in allocation of patients to two drug groups(phenylephrine and ephedrine).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Kermanshah University of Medical Sciences
Street address
No. 2 building of Medical University, Shahid Beheshti boulevard
City
kermanshah
Postal code
00988334276310
Approval date
2015-08-18, 1394/05/27
Ethics committee reference number
KUMS.REC.1394.52

Health conditions studied

1

Description of health condition studied
headache
ICD-10 code
G44.4
ICD-10 code description
Drug-induced headache, not elsewhere classified

Primary outcomes

1

Description
headache incidence and intencity
Timepoint
during cesarean, 1, 6, 24 hours later
Method of measurement
by visual analogue scale

Secondary outcomes

1

Description
vital sign changes
Timepoint
every 2 minute until 10minute then every 5 minute
Method of measurement
by datascope monitor

Intervention groups

1

Description
Ephedrine ampule 10 mcgr, Intravenous, repeated until hemodynamic stability
Category
Prevention

2

Description
Phenylephrine ampule 50 mcgr, Intravenous, repeated until hemodynamic stability in the first case group
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Dr. Mitra Yari
Street address
Parastar boulevard, Sorkhalijeh
City
kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for reasearch ,Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Imam Reza Hospital, Parastar boulevard, Sorkhalijeh

City

kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for reasearch ,Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Mitra Yari

Position

assistant professor, anesthesiologist

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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