

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Evaluation of the effect of pseudo ephedrine in prevention of decrease of blood pressure due to spinal anesthesia during elective cesarean section

Protocol summary

Summary

The aim of this study: Evaluation of the effect of pseudo ephedrine in prevention of decrease of blood pressure due to spinal anesthesia during elective cesarean section. Study design: After explaining the purpose of the study and obtaining the informed consent, patients will be allocated into A and B groups. The study is double blind, single-center, phase 3 trial. Inclusion criteria: Pregnant women candidates for spinal anesthesia cesarean section. Exclusion criteria: Systolic blood pressure more 120 mm Hg or lower than 60 mm Hg; diabetes; thyroid disease; beta agonist and beta blocker use; preeclampsia; eclampsia; preterm labor. Sample size: 60 patients are participated in the study with 30 patients in each group. Intervention group: pseudo ephedrine syrup 60 mg. Primary outcome: decrease of blood pressure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042733664N1**

Registration date: **2017-08-12, 1396/05/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-12, 1396/05/21

Registrant information

Name

Aylar Havazyari

Name of organization / entity

Islamic Azad University of Shahrood

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Islamic Azad University of Shahrood

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of pseudo ephedrine in prevention of decrease of blood pressure due to spinal anesthesia during elective cesarean section

Public title

The effect of pseudo ephedrine in prevention of decrease of blood pressure due to spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women candidates for spinal anesthesia cesarean section Exclusion criteria: Systolic blood pressure more 120 mm Hg or lower than 60 mm Hg; diabetes; thyroid disease; beta agonist and beta blocker use; preeclampsia; eclampsia; preterm labor

Age

No age limit

Gender

Female

Phase

3

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

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Shahrood

Street address

Islamic Azad University of Shahrood, Tehran Blvd, Shahrood

City

Shahrood

Postal code

Approval date

2016-11-10, 1395/08/20

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1395.5

Health conditions studied

1

Description of health condition studied

spinal anaesthesia

ICD-10 code

O74.5

ICD-10 code description

Spinal and epidural anaesthesia-induced headache during labour and delivery

Primary outcomes

1

Description

Blood pressure

Timepoint

Before intervention and every 5 minute after intervention until 40 minute

Method of measurement

Mercury milimeter with mercurous gauge

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Single dose of 60 mg pseudoephedrine syrup before spinal anaesthesia

Category

Treatment - Drugs

2

Description

Control group: No action

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

khatam Alanbia Hospital of Shahrood

Full name of responsible person

Yousef Kolukhi

Street address

khatam Alanbia Hospital, Tehran Blvd, Shahrood

City

Shahrood

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology, Islamic Azad University of Shahrood

Full name of responsible person

Sahebali Manafi

Street address

Islamic Azad University of Shahrood, Tehran Blvd

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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

Vice chancellor for Research and Technology, Islamic Azad University of Shahrood

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

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Shahrood

City**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