

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

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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

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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

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khatam Alanbia Hospital, Tehran Blvd, Shahrood

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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

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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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Full name of responsible person

Yousef Kolukhi

Position

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Other areas of specialty/work**Street address**Tehran Blvd, Shahrood Islamic Azad University,
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*