

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the effects of ephedrine, atropine and mucosal phenylephrine perfusion in preventing hypotension during spinal anesthesia for ceasarean section.

Protocol summary

Summary

Occurrence of hypotension after spinal anaesthesia is common. This study aims to find the most effective way of preventing hypotension that occurs after spinal anaesthesia and its subsequent complications. Preventing the hypotension associated with spinal anaesthesia could produce a better condition for the operation and surgery could be done with less end organ damage and higher safety level. Materials and Methods: This is a randomized double blind prospective study with 3 groups. Ninety young adult female, ASA physical status 1 and 11 with single pregnancy undergoing elective caesarean section under spinal anaesthesia divided into 3 groups. All of the groups will receive 500 ml ringer serum before spinal anaesthesia. The first group will receive 0.5 mg atropine (IV), the second group will receive 5mg ephedrine and the last group will receive 100µgr phenylephrine (mucosal). Blood pressure, heart rate, oxygen saturation and side effects were recorded before spinal anaesthesia, and every 5 minutes throughout the operation up to 30 minutes. After that recordings will be at 15 minutes interval until 1.5 hours after spinal anaesthesia. If systolic blood pressure comes to less than 80 mmHg we will get the patients 5 mg ephedrine. Key Words: Anaesthesia, Caesarean, Prophylaxis, Atropine, Ephedrine, phenylephrine

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902213912N1**

Registration date: **2010-06-15, 1389/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-06-15, 1389/03/25

Registrant information

Name

Kobra Nourian

Name of organization / entity

Sharekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 5648

Email address

noorian@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2006-12-22, 1385/10/01

Expected recruitment end date

2007-05-22, 1386/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of ephedrine, atropine and mucosal phenylephrine perfusion in preventing hypotension during spinal anesthesia for ceasarean section.

Public title

Comparison of the effects of ephedrine, atropine and mucosal phenylephrine perfusion in preventing

hypotension during spinal anesthesia for cesarean section.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria consisted of age between 20-40 years, ASA physical status 1 and 11, single pregnancy, elective cesarean, gestational age ≥ 37 weeks and patients satisfaction. Exclusion criteria consisted of hypovolemia, deformity of spinal column, increase of ICP, coagulopathy, infection of skin or soft tissue and unsatisfaction of patient .

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

This is a double blind study because both the patients and the officer responsible for measuring outcomes are unaware of the intervention received by patient.

Secondary Ids

empty

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

Shahrekord University of Medical Sciences

Street address

Shahrekord -kashane street-university of medical sciences

City

Shahrekord

Postal code

8813833435

Approval date

empty

Ethics committee reference number

86-312

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

Single delivery cesarean

ICD-10 code

O82.0

ICD-10 code description

Single delivery by caesarean section

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

blood pressure

Timepoint

before spinal anesthesia and every 5 minutes interval through out the surgery until 30 minutes, therefore at 15 minutes interval until 1.5 hours after spinal

Method of measurement

pulse oxymetry

2**Description**

heart rate

Timepoint

before spinal anesthesia and every 5 minutes interval through out the surgery until 30 minutes, therefore at 15 minutes interval until 1.5 hours after spinal

Method of measurement

pulse oxymetry

3**Description**

oxygen saturation

Timepoint

before spinal anesthesia and every 5 minutes interval through out the surgery until 30 minutes, therefore at 15 minutes interval until 1.5 hours after spinal

Method of measurement

pulse oxymetry

Secondary outcomes

empty

Intervention groups**1****Description**

0.5 mg atropine (IV) before spinal anesthesia (single dose)

Category

Treatment - Drugs

2

Description

5mg ephedrine before spinal anesthesia(single dose)

Category

Treatment - Drugs

3

Description

100µgr phenylephrine (mucosal) before spinal anesthesia (single dose)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Mitra Talebpoor

Street address

Parastar Street-Hajar Hospital-Surgery Department

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Reserch Center

Street address

Kashani Street.University of Medical Sciences

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrekord 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

Shahrekord University of Medical Sciences

Full name of responsible person

Cobra Noorian

Position

Lecturer, Nursing Dept, Shahrekord University of Medical Sciences

Other areas of specialty/work

Street address

Nursing department, Shahrekord University of Medical Sciences

City

Shahrekord

Postal code

8813833435

Phone

+98 38 1333 5648

Fax

+98 38 1334 6714

Email

noorian@skums.ac.ir; cobranori@yahoo.com

Web page address

www.skums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Mohammamad Reza Abedinzadeh

Position

Assistant Proffesr

Other areas of specialty/work

Street address

Assistant proffesr, Anesthesiology Dept, Shahrekord University of Medical Sciences

City

shahrekord

Postal code

8815713471

Phone

+98 38 1333 5552

Fax

+98 38 1334 6714

Email

abedinzade@skums.ac.ir

Web page address

www.skums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Cobra Noorian

Position

Lecturer, Nursing Dept, Shahrekord University of
Medical Sciences

Other areas of specialty/work

Street address

Rahmateieh- Shahrekord University of Medical
Sciences

City

Shahrekord

Postal code

8813833435

Phone

+98 38 1333 5648

Fax

+98 38 1334 6714

Email

noorian@skums.ac.ir

Web page address

www.skums.ac.ir

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