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 3groups. 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

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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 ceasarean section.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria consisted of age between 20-40 years, ASAphysical status 1 and 11, single pregnancy, elective ceasarean, gestational age≥37weeks and patients satisfaction. Exclusion criteria consisted of hypovolemia, deformity of spinal column, increase of ICP, coaglopathy, 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 ceasarean

ICD-10 code
O82.0

ICD-10 code description
Single delivery by caesarean section

Primary outcomes

1

Description
blood pressure

Timepoint
before spinal anesthesia andevery 5 minutes interval through out the surgery until 30 minutes,therefore at 15minutes interval until 1.5 hourrs after spinal

Method of measurement
palseoxymetery

2

Description
heart rate

Timepoint
before spinal anesthesia andevery 5 minutes interval through out the surgery until 30 minutes,therefore at 15minutes interval until 1.5 hourrs after spinal

Method of measurement
palseoxymetery

3

Description
oxygen saturation

Timepoint
before spinal anesthesia andevery 5 minutes interval through out the surgery until 30 minutes,therefore at 15minutes interval until 1.5 hourrs after spinal

Method of measurement
palse oxymetery

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
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Parastar Street-Hajar Hospital-Surgery Department
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University of Medical Sciences
Full name of responsible person
Reserch Center
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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

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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