Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The comparison of different prophylactic techniques in hypotension due to spinal anesthesia on blood pressure and heart rate of parturients undergoing cesarean section

Protocol summary

Summary

The aim of this clinical trial was evaluation the efficacy of six combinational methods for preventing maternal hypotension after spinal anesthesia for cesarean delivery. A total of 300 ASA physical status I-II women undergoing elective cesarean section with spinal anesthesia were randomized to six groups: 1-Ringer's lactate (RL) solution (15 ml/kg) and colloid (Hemaxel) preload (7ml/kg); 2- RL solution preload (15 ml/kg) and ephedrine(15 mg, IV, bolus); 3-RL solution preload (15 ml/kg) and leg bandage; 4-Colloid (Hemaxel) preload (7ml/kg) and ephedrine(15 mg, IV, bolus); 5-Colloid (Hemaxel) preload (7ml/kg) and leg bandage; 6-Ephedrine (15 mg, IV, bolus)and leg bandage.The crystalloid and colloid solution infused 30 minutes before spinal anesthesia and ephedrine and leg bandage administered immediately after spinal anesthesia in above groups.Spinal anesthesia was done using bupivacaine 0.5 percent 2.5 ml in all patients. Participants were including parturients with ASA physical status I-II, scheduled for elective cesarean section, under spinal anesthesia and excluded with suspicious to bleeding disturbances, atopia, diabetes mellitus, presence of liver or kidney diseases, drugs abuse, hypertension of pregnancy, preeclampsia. Maternal blood pressure and heart rate compared on arrival to operating room, immediately after anesthesia (time 0), and minutes 3, 5, 15, 20, 25, 30, 35, and 60 after spinal injection among the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201107062405N7**
Registration date: **2011-07-13, 1390/04/22**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2011-07-13, 1390/04/22

Registrant information

Name

Mitra Jabalameli

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2004-05-31, 1383/03/11

Expected recruitment end date

2008-02-11, 1386/11/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of different prophylactic techniques in hypotension due to spinal anesthesia on blood pressure and heart rate of parturients undergoing cesarean section

Public title
The comparison of different prophylactic techniques in hypotension due to spinal anesthesia on mother"s hemodynamic changes and neonatal outcome in cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: Parturients; ASA physical status I-II; scheduled for elective cesarean section; under spinal anesthesia; Exclusion Criteria: suspicious to bleeding disturbances; atopia; diabetes mellitus; presence of liver or kidney diseases; drugs abuse; hypertension of pregnancy; preeclampsia
Age
From **15 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **300**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-chancellor for Research, Ethics committee of Isfahan University of Medical Sciences
Street address
Vice-chancellor for Research, Isfahan University of Medical Sciences
City
Isfahan
Postal code
00
Approval date
2004-05-31, 1383/03/11
Ethics committee reference number
83036

Health conditions studied

1

Description of health condition studied
Complications of anaesthesia during pregnancy
ICD-10 code
O29.8
ICD-10 code description
Other complications of anaesthesia during pregnancy

Primary outcomes

1

Description
Systolic blood pressure
Timepoint
On arrival to operating room, immediately after anesthesia (time 0), and minutes 3, 5, 15, 20, 25, 30, 35, and 60 after spinal injection
Method of measurement
Using mercury manometer

2

Description
Heart rate
Timepoint
On arrival to operating room, immediately after anesthesia (time 0), and minutes 3, 5, 15, 20, 25, 30, 35, and 60 after spinal injection
Method of measurement
Using EKG Monitoring

Secondary outcomes

1

Description
Apgar score
Timepoint
at min 1 and 5
Method of measurement
Apgar score mesurements by physical examination

2

Description
NACS
Timepoint
at 15 minutes, 2 hours, and 24 hours after delivery
Method of measurement
NACS mesurements by physical examination

Intervention groups

1

Description
Ringer's lactate (RL) solution (15 ml/kg) was infused. Duration of treatment: single dose in 30 minutes before

spinal injection + mid thigh-high lower extremities bandage was performed immediately after spinal injection. Duration of treatment: During spinal anesthesia in operating room

Category

Prevention

2

Description

Colloid solution (Hemaxel) (7ml/kg) was infused. Duration of treatment: single dose in 30 minutes before spinal injection + mid thigh-high lower extremities bandage was performed immediately after spinal injection. Duration of treatment: During spinal anesthesia in operating room

Category

Prevention

3

Description

Ephedrine (15 mg, IV, bolus) was infused in 45 seconds. Duration of treatment: single dose Immediately after spinal injection+ mid thigh-high lower extremities bandage was performed immediately after spinal injection. Duration of treatment: During spinal anesthesia in operating room

Category

Prevention

4

Description

Ringer's lactate (RL) solution (15 ml/kg) was infused. Duration of treatment: single dose in 30 minutes before spinal injection + colloid solution (Hemaxel) (7ml/kg) was infused. Duration of treatment: single dose in 30 minutes before spinal injection

Category

Prevention

5

Description

Ringer's lactate (RL) solution (15 ml/kg) was infused. Duration of treatment: single dose in 30 minutes before spinal injection + Ephedrine (15 mg, IV, bolus) was infused in 45 seconds. Duration of treatment: single dose Immediately after spinal injection

Category

Prevention

6

Description

Colloid solution (Hemaxel) (7ml/kg) was infused. Duration of treatment: single dose in 30 minutes before spinal injection + Ephedrine (15 mg, IV, bolus) was infused in 45 seconds. Duration of treatment: single dose Immediately after spinal injection

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Medical Center

Full name of responsible person

Dr. Mitra Jabalameli

Street address

Department of Anesthesia and intensive care, Alzahra General Hospital, Sofe Boulevard

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research- Isfahan University of Medical Sciences

Full name of responsible person

Dr. Payman Adibi

Street address

Vice-chancellor for Research, Isfahan University of Medical Sciences- Hezar Jarib St.

City

Isfahan

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- Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Mitra Jabalameli

Position

Specialist and Associate professor of Anesthesia and intensive care

Other areas of specialty/work

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Web page address

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