Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison the Hemodynamic Effects of Spinal Anesthesia with Bupivacaine-Fentanyl in Pre-eclamptic Versus Normal Pregnant women

Protocol summary

Summary

The aim of this study was determination and comparison the hemodynamic changes due to spinal anesthesia in pre-eclamptic patients and normal pregnant women during elective cesarean section. In design of the study, 35 pre-eclamptic patients and 35 normal pregnant women were selected for elective cesarean section under spinal anesthesia. Before spinal anesthesia, all patients received 8-10 ml/kg Ringer's solution. For spinal anesthesia in both groups, 2 ml bupivacaine 0.5% (10mg) and 2 ml fentanyl (20µg) were administered in subarachnoid space through the needle number 25 at the level of L4-L5 in the sitting position. The participants of the study were pre-eclamptic or normal pregnant women between 18 and 45 years old. In the presence of patient refusal of spinal anesthesia, fetal distress, and symptom of sever pre-eclampsia (convulsion, pulmonary edema, headache, visual disturbance, impaired consciousness and coagulopathy), patients were excluded from study. Blood pressure and heart rate after spinal anesthesia were measured every 5 minutes until 30 minutes after operation in the recovery room and then were compared with each other in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201304157695N3**
Registration date: **2013-07-23, 1392/05/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-07-23, 1392/05/01

Registrant information

Name

Seyedeh Masoumeh Hosseini Valami

Name of organization / entity

Qazvin University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Hemodynamic Effects of Spinal Anesthesia with Bupivacaine-Fentanyl in Pre-eclamptic Versus Normal Pregnant women

Public title

Hemodynamic Changes of Spinal Anesthesia in Pre-eclampsia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women with age range of 18-45 years old Exclusion criteria: Patient refusal of spinal anesthesia, presence of: fetal distress, convulsion,

pulmonary edema, headache, visual impairment, impaired consciousness, coagulopathy, high systemic blood pressure (BP>170/110), systemic involvement (diabetes mellitus, chronic hypertension), positive history of antihypertensive drugs consumption

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
Shahid Bahonar Blvd, Qazvin

City
Qazvin

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
28/20/7241

Health conditions studied

1

Description of health condition studied
Pre-eclampsia

ICD-10 code
O14.0

ICD-10 code description
Moderate Pre-eclampsia

Primary outcomes

1

Description
Blood pressure and heart rate

Timepoint
After spinal anesthesia, every 5 minutes during operation until 30 minutes after operation in recovery period

Method of measurement
By noninvasive cardiovascular monitoring, blood pressure and heart rate were measured and recorded in questionnaire

Secondary outcomes

1

Description
Shivering

Timepoint
Recovery period

Method of measurement
By observational method (mild, moderate and sever) was determined and recorded in questionnaire

2

Description
Nausea, vomiting

Timepoint
During operation until 30 minutes after operation in recovery period

Method of measurement
By observational method (mild, moderate and sever) was determined and recorded in questionnaire

3

Description
Postoperative Pain

Timepoint
During 30 minutes after operation in recovery period

Method of measurement
By Visual Analog Scale was determined and recorded in questionnaire

4

Description
Apgar score

Timepoint
First and fifth minute

Method of measurement
By numbering method (1-10) was determined and recorded in questionnaire

Intervention groups

1

Description

In the first group (normal pregnant patients), 2 ml bupivacaine 0.5% (trademark marcaine, made in Merck factory in France) and 2 ml fentanyl (20µg) was administered intrathecally as a single dose.

Category

Prevention

2

Description

In the second group (pre-eclamptic patients), 2 ml bupivacaine 0.5% (trademark marcaine, made in Merck factory in France) and 2 ml fentanyl (20µg) was administered intrathecally as a single dose.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kowsar Hospital

Full name of responsible person

Seyedeh Masoumeh Hosseini Valami M.D.

Street address

Kowsar Hospital, Qazvin

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Saeed Assefzadeh

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd , Qazvin

City

Qazvin

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 of Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Abbas Hosseini Jahromi M.D.

Position

Anesthesiologist / Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Associate Professor

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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