

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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.

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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**

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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 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**

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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*