Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparing the hemodynamic effects of spinal anesthesia in cesarean section of severely preeclamptic patients and healthy parturients

Protocol summary

Summary

This prospective single center clinical trial was designed to compare the hemodynamic effects of low-dose spinal bupivacaine in severely preeclamptic versus healthy parturients undergoing cesarean section. A total of 80 pregnant women with severe preeclamsia and healthy parturients who are candidates for termination of pregnancy with cesarean section are recruited in this study. In both groups of pregnant women, spinal anesthesia is performed with 10 mg hyperbaric %0.5 bupivacaine plus 5 µg sufentanil after receiving 500 ml of IV Ringer's solution. Heart rate and blood pressure were recorded before spinal anesthesia, every 2 minutes for 15 minutes then every 5 minutes until the end of the surgery. Primary outcome is hypotension that is defined as more than 30% decline in mean arterial blood pressure compared to baseline blood pressure in both groups (or systolic blood pressure <100 mmHg in healthy parturients).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101275709N1**
Registration date: **2011-03-24, 1390/01/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-03-24, 1390/01/04

Registrant information

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Razieh Dastaran

Name of organization / entity

Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Scienece-Research Vice Chancellorship

Expected recruitment start date

2008-04-20, 1387/02/01

Expected recruitment end date

2011-03-05, 1389/12/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the hemodynamic effects of spinal anesthesia in cesarean section of severely preeclamptic patients and healthy parturients

Public title

Effects of spinal anesthesia in cesarean section of severe preeclamptic patients

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women with severe pre-eclamsia and healthy parturients who are candidate for termination of pregnancy with cesarean section
Exclusion criteria: Presence of coagulopathy (platelet less than 50000); placental abruption; severe fetal distress; history of allergy to local anesthetics; skin infection of injection site and no satisfaction of patients

for regional anesthesia

Age

From **14 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

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

Hamedan Univercity of Medical Science

Street address

Hamedan Univercity of Medical science-Shahid Fahmideh boulevard-Hamedan

City

Hamedan

Postal code

Approval date

2008-11-22, 1387/09/02

Ethics committee reference number

116450/9/35/16/پ

Health conditions studied

1

Description of health condition studied

Severe preeclampsia

ICD-10 code

014.1

ICD-10 code description

Gestational [pregnancy-induced] hypertension with significant proteinuria

Primary outcomes

1

Description

Blood pressure

Timepoint

Before spinal anesthesia, every 2 minutes for 15 minutes then every 5 minutes until the end of surgery

Method of measurement

According to hydragyr millimeter with hydragyric manometer ALP-K2 model

Secondary outcomes

1

Description

Neonate condition

Timepoint

One and five minute after birth

Method of measurement

APGAR score

Intervention groups

1

Description

Spinal anesthesia was performed with 10 mg hyperbaric %0.5 bupivacaine plus 5 µg sufentanil in two groups after receiving 500 ml of IV Ringer's solution

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Fatemieh Hospital

Full name of responsible person

Street address

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Scienece-Research Vice Chancellorship

Full name of responsible person

Dr.Ali Ghaleiha

Street address

Hamedan University of Medical Scienece-Research Vice Chancellorship -Shahid Fahmideh boulevard-Hamedan

City

Hamedan

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan University of Medical Scienece-Research Vice Chancellorship
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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Name of organization / entity
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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