

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effect of intrathecal injection rate of bupivacaine 0.5% on maternal sensory level and hypotension during elective cesarean delivery under spinal anesthesia.

Protocol summary

Summary

Spinal anesthesia with hyperbaric bupivacaine is an option that commonly used for elective cesarean delivery to reduce adverse effect of general anesthesia. The purpose of this study was to evaluate the influence of injection rate of bupivacaine 0.5% on anesthesia characteristics in parturient. Method: In this prospective study 75 term parturient allocated randomly to 3 groups according to rate of injection of 10 mg hyperbaric bupivacaine and 2.5 µg sufentanil with total volume of 3 ml; Group F (High injection rate, 1ml/s), Group S (Slow injection rate, 0.04 ml/s) and Group M (Moderate injection rate, 0.2 ml/s). Primary outcomes are systolic and diastolic blood pressure, Heart rate, Sensory level and Motor level.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122210841N2**

Registration date: **2013-02-03, 1391/11/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-02-03, 1391/11/15

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

School of Medicine, Hamadan University Of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-11-19, 1391/08/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intrathecal injection rate of bupivacaine 0.5% on maternal sensory level and hypotension during elective cesarean delivery under spinal anesthesia.

Public title

Evaluation of drug injection rate on hypotension incidence during spinal anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with ASA class 1&2; 18-40 years old; term pregnancy >37 week ; patients scheduled for elective cesarean section under spinal anesthesia. Exclusion criteria: Twin pregnancy ; emergency cesarean section ; pre-eclampsia; eclampsia & maternal hypertension; cardiac disease; contraindications for spinal anesthesia (patients refusal, increase of ICP, skin infection, coagulation disease, hypovolemia, previous

neural problems and inexperienced anesthetologist)

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

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

Hamadan University Of Medical Sciences

Street address

School of Medicine, Shahid Fahmide Street

City

Hamadan

Postal code

65178

Approval date

2012-12-15, 1391/09/25

Ethics committee reference number

3254/9/35/16/د/پ

Health conditions studied

1

Description of health condition studied

Bupivacaine injection rate in spinal anesthesia

ICD-10 code

O29.5

ICD-10 code description

Other complications of spinal and epidural anaesthesia during pregnancy

Primary outcomes

1

Description

Systolic Blood Pressure

Timepoint

Systolic blood pressure was measured every 1 minute up to 15 minutes after spinal anesthesia and every 5 minutes up to 30 minutes and every 10 minutes up to end of surgery (60 minutes).

Method of measurement

using non invasive blood pressure monitoring

2

Description

Diastolic Blood Pressure

Timepoint

Diastolic blood pressure was measured every 1 minute up to 15 minutes after spinal anesthesia and every 5 minutes up to 30 minutes and every 10 minutes up to end of surgery (60 minutes).

Method of measurement

Non invasive Blood Pressure Monitoring

3

Description

Heart rate

Timepoint

Heart rate was measured every 1 minute up to 15 minutes after spinal anesthesia and every 5 minutes up to 30 minutes and every 10 minutes up to end of surgery (60 minutes).

Method of measurement

Pulse oximetry

4

Description

Sensory level

Timepoint

after spinal anesthesia and before surgery

Method of measurement

With needle in anterior axillary line and bilateral.

5

Description

Motor level

Timepoint

After spinal anesthesia and before surgery

Method of measurement

Observation & Examination and Bromage score (0 = no motor block, 1 = inability to raise the extended leg, 2 = inability to flex the knee, 3 = inability to flex the ankle)

Secondary outcomes

1

Description

Nausea

Timepoint

During surgery
Method of measurement
Observation

2

Description
Vomiting
Timepoint
during surgery
Method of measurement
Observation

3

Description
Efedrine Dosage
Timepoint
Ending of surgery
Method of measurement
Measurement of efedrine

Intervention groups

1

Description
Moderate group patients recieved 750 ml serum Ringer and anesthetized with spinal anesthesia in sitting position . 10 mg bupivacaine %0.5(2/5 ml)combined 0/5ml sufentanil(total volume=3ml) by 25 Gneedle in L3-L4 or L4-L5 space and injection rate (0/2 ml/second) was injected.
Category
Prevention

2

Description
Fast group patients recieved 750 ml serum Ringer and anesthetized with spinal anesthesia in sitting position . 10 mg bupivacaine %0.5(2/5 ml)combined 0/5ml sufentanil(total volume=3ml) by 25 Gneedle in L3-L4 or L4-L5 space and injection rate (1ml/second)was injected.
Category
Prevention

3

Description
Slow group patients recieved 750 ml serum Ringer and anesthetized with spinal anesthesia in sitting position . 10 mg bupivacaine %0.5(2/5 ml)combined 0/5ml sufentanil(total volume=3ml) by 25 Gneedle in L3-L4 or L4-L5 space and injection rate (0/04 ml/second) was injected.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemy Hospital
Full name of responsible person
Nahid Manouchehrian
Street address
Fatemy Hospital, Pasdaran Street
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Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research
Full name of responsible person
Dr. Heidar Tavilany
Street address
Hamadan university of medical science, School of Medicine, Fahmide Street
City
Hamadan
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
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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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