# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## A comparison of the sensory and motor blockade duration of intrathecal, Bupivacaine-Sulfate Mg and Bupivacaine alone

## Protocol summary


**Summary**

In this study the effect of intrathecal sulfate magnesium on duration of motors & sensory block was evaluated. Design: Duble blind clinical trial. Setting: Patients were divided into two groups randomly Bupivacaine - Sulfate magnesium and Bupivacaine alone. All patients was given serum ringer 500ml before spinal anesthesia. Inclusion criteria: eighty ASA class I,II full term pregnant women who require for elective cesarean section. Exclusion criteria:Patients with a history of cardiovascular disease; psychiatric; chronic pain; dependent on drugs and alcohol; HTN; DM and other systemic disease. Intervention: Patients were randomly allocated to receive intrathecally either 10mg Hyperbaric Bupivacaine plus 0.1ml(50mg) sulfate magnesium 50% or 10mg Hyperbaric Bupivacaine plus 0.1ml N/S 0.9% Main outcomes:BP, HR, Nausea & vomiting, duration of sensory & motor block.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201312124923N5**
Registration date: **2014-01-02, 1392/10/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2014-01-02, 1392/10/12

**Registrant information**


**Name**

Bahman Hasannasab

**Name of organization / entity**

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**Recruitment status**

**Recruitment complete**

**Funding source**

vice-chancellor Of Research Babol University Of Medical Sciences

**Expected recruitment start date**

2003-12-22, 1382/10/01

**Expected recruitment end date**

2014-03-20, 1392/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparison of the sensory and motor blockade duration of intrathecal, Bupivacaine-Sulfate Mg and Bupivacaine alone

**Public title**

A comparison of the sensory and motor blockade duration of intrathecal, Bupivacaine-Sulfate Mg and Bupivacaine alone

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: ASA class I,II; Height 160 to 180 cm; candidates for elective caesarean section; gestational age over 39 weeks Exclusion criteria: Patients with a history of cardiovascular disease; psychiatric; chronic pain; dependent on drugs and alcohol; HTN; DM and other systemic disease.

**Age**

No age limit

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**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**

Ethics committee of Babol University Of Medical Sciences

**Street address**

Daneshgah Square, Ganjafrooz Avenue

**City**

Babol

**Postal code**

**Approval date**

2013-12-21, 1392/09/30

**Ethics committee reference number**

3480/30/ژ/پ

## Health conditions studied

### 1

**Description of health condition studied**

Cesarean section

**ICD-10 code**

O74

**ICD-10 code description**

Complications of anaesthesia during labour and delivery

## Primary outcomes

### 1

**Description**

Evaluation of Sensory block duration

**Timepoint**

Sensory block level evaluated every 30 second until 15 minutes and then 5 minutes until sensory block off

**Method of measurement**

Needle No 20

### 2

**Description**

Evaluation of motor block duration

**Timepoint**

motor block level evaluated every 30 second until 15 minutes and then 5 minutes until motor block off

**Method of measurement**

Bromage scale

## Secondary outcomes

### 1

**Description**

Blood pressure

**Timepoint**

0, 1, 3, 6, 9, 12, 15, 18 and 21 min

**Method of measurement**

Non Invasive BP

### 2

**Description**

Heart rate

**Timepoint**

0, 1, 3, 6, 9, 12, 15, 18 and 21 min

**Method of measurement**

ECG

### 3

**Description**

Analgesia

**Timepoint**

first 24 hours after spinal

**Method of measurement**

VAS

## Intervention groups

### 1

**Description**

Intervention group: Patients were randomly allocated to receive intrathecally either 10mg Hyperbaric Bupivacaine plus 0.1ml(50mg) sulfate magnesium 50%

**Category**

Treatment - Drugs

### 2

**Description**

Control group:Patients with 10 mg Intrathecal Bupivacaine with 0.1 ml of normal saline is injected.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Ayatollah Ruhani Hospital
**Full name of responsible person**
Dr Bahman hasannasab
**Street address**
Daneshgah Square, Ganjafrooz Avenue
**City**
Babol

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice-chancellor Of Research Babol University Of Medical Sciences
**Full name of responsible person**
Dr Amrolah Mostafazadeh
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Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
**City**
Babol
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vice-chancellor Of Research Babol 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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*