Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 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

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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
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Daneshgah Square, Ganjafrooz Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor Of Research Babol University Of Medical Sciences
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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 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

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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