

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of 10 and 12 mg doses of intrathecal bupivacaine %0.5 on sensory block level and postdural puncture headache in patients under repeated spinal after failed spinal anesthesia in C/S.

Protocol summary

Study aim

Comparison of 10 and 12 mg doses of intrathecal bupivacaine %0.5 on sensory block level and postdural puncture headache in patients under repeated spinal after failed spinal anesthesia in Cesarean Section

Design

In this double-blind study, 40 patients aged 18-46 years old with a cesarean section at Fatemiyeh Hospital of Hamadan were enrolled in the study after obtaining informed consent

Settings and conduct

The study will be conducted at Fatemiyeh Hospital in Hamadan. Patients will be randomly divided into two groups, In group A, patients undergoing spinal anesthesia with 10 mg bupivacaine 0.5 % and in group B, they undergo spinal anesthesia with 12 mg bupivacaine 0.5%.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient's consent to participate in the study; No history for diabetes, high blood pressure, heart disease; Patients who have failed spinal anesthesia and undergo general anesthesia. Exclusion criteria: Patients with contraindications of spinal anesthesia (ICP increase, shock, history of coagulation problems ...).

Intervention groups

In group A, patients undergoing spinal anesthesia with 10 mg bupivacaine 0.5 % and in group B, they undergo spinal anesthesia with 12 mg bupivacaine 0.5%.

Main outcome variables

sensory block, Headache

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120915010841N20**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **retrospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Nahid Manouchehrian

Name of organization / entity

Hamedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1827 7012

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manouchehrian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-23, 1397/04/02

Expected recruitment end date

2019-06-23, 1398/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of 10 and 12 mg doses of intrathecal bupivacaine %0.5 on sensory block level and postdural puncture headache in patients under repeated spinal

after failed spinal anesthesia in C/S.

Public title

Comparison of 10 and 12 mg doses of intrathecal bupivacaine %0.5 on sensory block level and postdural puncture headache in patients under repeated spinal

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Patient's consent to participate in the study No history for diabetes, high blood pressure, heart disease Patients who have failed spinal anesthesia and undergo general anesthesia

Exclusion criteria:

Patients with contraindications of spinal anesthesia (ICP increase, shock, history of coagulation problems ..)

Age

From **18 years** old to **48 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study , a randomized block design with four replications is used. we provide four paper sheets . We write two letters A and on two other sheets of letter B. We mix the papers together and put them in the drawer of the table. With each of the qualified patients, one of the papers is taken out randomly and will be assigned to one of the two Bupivacaine 10 and Bupivacaine 12 mg groups, depending on whether the drawn sheet is either A or B. After the random drawn out of four sheets, all the papers will be returned to the drawer and again the above procedure will continue for the next four patients until it reaches the sample volume.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants knew the purpose of the study, but did not know which dose of bupivacaine would receive and the researcher did not know the dose.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Mahdieh Street

City

Hamadan

Province

Hamadan

Postal code

6517838678

Approval date

2019-06-15, 1398/03/25

Ethics committee reference number

IR.UMSHA.REC.1398.232

Health conditions studied

1

Description of health condition studied

Spinal anesthesia in cesarean section

ICD-10 code

Z38.01

ICD-10 code description

Single liveborn infant, delivered by cesarean

Primary outcomes

1

Description

Quality motor block

Timepoint

5-10-15 and 30 minutes after analgesia

Method of measurement

Bromage score

2

Description

Sensory block quality

Timepoint

5-10-15 and 30 minutes after analgesia

Method of measurement

visual analgesic scale

3

Description

Headache

Timepoint

A week after surgery

Method of measurement

visual analgesic scale

Secondary outcomes

1

Description

Nausea & vomiting

Timepoint

after delivery

Method of measurement

Observation

2

Description

new born Apgar

Timepoint

1&5 minutes after delivery

Method of measurement

Apgar Score

Intervention groups

1

Description

Intervention group: patients undergoing spinal anesthesia with 10 mg bupivacaine 0.5 %.

Category

Treatment - Drugs

2

Description

Intervention group: patients undergoing spinal anesthesia with 12 mg bupivacaine 0.5%.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Nahid Manouchehrian

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Pasdaran Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeed Bashirian

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Grant name

Hamedan University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Nahid Manouchehrian

Position

associated professor of anesthesia Department

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available