Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of Sensory and Motor Block Efficacy at Different Reverse Trendelenburg Angles in Patients Undergoing Spinal Anesthesia with Heavy Marcain

Protocol summary

Study aim

In this study, the sensory and motor blockade effects of hyperbaric bupivacaine applied to patients undergoing anorectal surgery were compared in reverse trandelenburg position at 0, 10, 30, 50, 70 and 90 degree back angles.

Design

Heavy bupivacaine is frequently used in the surgical field for subarochnoid block. While bupivacaine is the 0.5% plain form that does not contain dextrose, the hyperbaric form is the form that emerges with the addition of glucose (80 mg/ml) to plain bubivacaine. The effectiveness of hyperbaric bupivacaine has been studied in many studies, and the sensory block pattern has been observed to be more predictable in hyperbaric bupivacaine than in bupivacaine. Another difference between hyperbaric and plan bupivacaine is the nature and duration of motor block.

Settings and conduct

All patients were given 7 ml/kg 0.9% NaCl preoperatively. During the operation, patients underwent electrocardiography, non-invasive blood pressure and pulse-oximetry monitoring. With spinal anesthesia in a sitting position, a 25-gauge (G) pencil-tipped spinal needle (BD Quincke) was administered to the lumbosacral region and 2 cc (10 mg) hyperbaric bupivacaine was administered to the subarachnoid space from the L3-4 space.

Participants/Inclusion and exclusion criteria

ASA (American Society of Anesthesiologists) I-II patients, aged between 18-50, who were planned for elective anorectal surgery, were included in the study. Patients who were morbidly obese, used anticoagulants or salicylates, had coagulation disorders, or had psychiatric or neurological problems were not included in the study.

Intervention groups

6 groups, 150 patients

Main outcome variables

In this study, the sensory and motor blockade effects of hyperbaric bupivacaine applied to patients undergoing anorectal surgery were compared in reverse trandelenburg position at 0, 10, 30, 50, 70 and 90 degree back angles.

General information

Reason for update

Acronym

Comparison of Sensory and Motor Block Efficacy

IRCT registration information

IRCT registration number: **IRCT20240204060903N1**
Registration date: **2024-02-24, 1402/12/05**
Registration timing: **retrospective**

Last update: **2024-02-24, 1402/12/05**
Update count: **0**

Registration date

2024-02-24, 1402/12/05

Registrant information

Name

yücel özgür

Name of organization / entity

Istanbul Bahcelievler State Hospital

Country

Turkey

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yucelozgur19@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-10, 1402/11/21

Expected recruitment end date

2024-02-12, 1402/11/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sensory and Motor Block Efficacy at Different Reverse Trendelenburg Angles in Patients Undergoing Spinal Anesthesia with Heavy Marcain

Public title

Comparison of Sensory and Motor Block Efficacy at Different Reverse Trendelenburg Angles in Patients Undergoing Spinal Anesthesia with Heavy Marcain

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

ASA (American Society of Anesthesiologists) I-II, 150 patients between the ages of 18-55 who are scheduled for elective anorectal surgery will be included in the study.

Exclusion criteria:

Patients who do not want to participate in the study will not be included in the study. Patients who use blood thinners and are pregnant will not be included in the study.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **150**

More than 1 sample in each individual

Number of samples in each individual: **25**

10 mg heavy bupivacaine will be administered to all groups in the subarochnoid space. There will be different angles in 6 groups

Randomization (investigator's opinion)

Randomized

Randomization description

People will be randomly divided into 6 groups. Working in groups will be done according to the plan according to the selected angle. Patients are randomly divided into groups. While patients are included in the groups, a blind evaluation will be made.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

People will be randomly divided into 6 groups. A study is planned in 150 patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bakırkoy Dr. Sadi Konuk Traınıng And Research Hospıtal| Clınıcal Studıes Ethıcs Commıttee Decısıon

Street address

Bahçelievler Mah Saklıvadi Sok. Ağaoğlu Mycity 30B2 D29

City

Bahçelıevler

Postal code

34180

Approval date

2023-06-05, 1402/03/15

Ethics committee reference number

245

Health conditions studied

1

Description of health condition studied

Istanbul Bahcelievler State Hospital

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

As a result of spinal anesthesia, block levels will vary depending on the patient's back angle.

Timepoint

Results will be collected from patients within 2 hours.

Method of measurement

The level of spinal block will be evaluated by cold test and pinprick test.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Patients in this group will be at 10,

30, 50, 70 and 90 degrees. 10 mg heavy marcain will be administered into the spinal space. Heavy bupivacaine is frequently used in the surgical field for subarachnoid block. While bupivacaine is a 0.5% plain form that does not contain dextrose, the hyperbaric form is the form that occurs with the addition of glucose (80 mg/ml) to plain bubivacaine. The effectiveness of hyperbaric bupivacaine has been studied in many studies, and the sensory block pattern has been observed to be more predictable in hyperbaric bupivacaine than in bupivacaine. Another difference between hyperbaric and plan bupivacaine is the nature and duration of the motor block. Hyperbaric bupivacaine generally has a safer level of effectiveness than bupivacane. In studies, the effectiveness of hyperbaric bupivacaine and other local anesthetic agents has been compared at different doses and in different surgeries, but no study comparing their effectiveness according to different angles in the supine reverse trandelenburg position of the patient has been found in the literature.The standard spinal anesthesia approach in anorectal surgery is performed in a sitting position and frequently with the application of hyperbaric bupivacaine. The applied doses are generally between 5-10 mg. Hyperbaric bupivacaine provides long-term pain relief in the postoperative period.

Category

Treatment - Surgery

2

Description

Control group: Patients in this group will be at 0 degrees. 10 mg heavy marcain will be administered into the spinal space.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Istanbul Bahçelievler State Hospital, Türkiye

Full name of responsible person

Yücel Özgür

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Istanbul Bahçelievler State Hospital, Türkiye

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

Istanbul Bahçelievler State Hospital

Full name of responsible person

Yücel Özgür

Position

Anesthesiology and Reanimation Clinic

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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
Not applicable

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