

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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

##### Phone

+90 505 524 21 40

##### Email address

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 science

**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 subarachnoid 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**  
Bakirkoy Dr. Sadi Konuk Training And Research Hospital| Clinical Studies Ethics Committee Decision  
**Street address**  
Bahçelievler Mah Saklıvadi Sok. Ağaoğlu Mycity 30B2 D29  
**City**  
Bahçelievler  
**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 bupivacaine. 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 plain bupivacaine is the nature and duration of the motor block. Hyperbaric bupivacaine generally has a safer level of effectiveness than bupivacaine. 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 Trendelenburg 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

##### Street address

Bahçelievler District

##### City

Istanbul

##### Postal code

34180

##### Phone

+90 505 524 21 40

##### Email

anstz@hotmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Istanbul Bahçelievler State Hospital, Türkiye

#### Full name of responsible person

yücel özgür

#### Street address

Bahçelievler District

#### City

istanbul

#### Postal code

34180

#### Phone

+90 505 524 21 40

#### Email

anstz@hotmail.com

#### 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

##### Street address

Bahçelievler District Saklıvadi Street Ağaoğlu Mycity  
30B2 D29

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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Istanbul Bahçelievler State Hospital

**Full name of responsible person**

Şenel Altun

**Position**

Cardiovascular Surgeon

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

**Street address**

Bahçelievler District

**City**

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**Province**

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**Postal code**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Istanbul Bahcelievler State Hospital

**Full name of responsible person**

Yücel özgür

**Position**

Doctor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Bahçelievler mah saklıvadi sok. ağaoğlu mycity 30B2  
D29

**City**

Bahçelievler

**Province**

İstanbul

**Postal code**

34180

**Phone**

+90 505 524 21 40

**Fax****Email**

yuceozgur19@gmail.com

## 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