

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

Comparison of anesthesia level of intrathecal injection after 1 and 1.5 cc bupivacaine 0.5% in saddle block

Protocol summary

Study aim

Comparison of anesthesia level of intrathecal injection after 1 and 1.5 cc bupivacaine 0.5% in saddle block

Design

A clinical trial without a control group, with parallel groups, without blinding, was randomized and 80 patients with a size of 4 blocks would be randomly assigned to two groups.

Settings and conduct

The study population was patients aged 18-65 years referred to the Babol Spiritual Educational and Medical Center. Patients are randomly divided into two groups using a random number table by computer. Intervention group1: To create nerve block, 1 cc bupivacaine 0.5% (Abu Reihan Pharmacy) is injected once into the intrathecal space. Intervention group2: To create nerve block, 1.5 cc bupivacaine 0.5% (Abu Reihan Pharmacy) is injected once into the intrathecal space.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: class I & II of Anesthesia Society of America (ASA) and patients candidate for elective perianal surgery. Exclusion Criteria: Cardiovascular disease, Chronic pain, lung disease, Opioids or alcohol dependency

Intervention groups

Intervention group1: To create nerve block, 1 cc bupivacaine 0.5% (Abu Reihan Pharmacy) is injected once into the intrathecal space. Intervention group2: To create nerve block, 1.5 cc bupivacaine 0.5% (Abu Reihan Pharmacy) is injected once into the intrathecal space.

Main outcome variables

Sensory block level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190529043750N3**

Registration date: **2021-06-28, 1400/04/07**

Registration timing: **prospective**

Last update: **2021-06-28, 1400/04/07**

Update count: **0**

Registration date

2021-06-28, 1400/04/07

Registrant information

Name

mohammad esmaeili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3233 8305

Email address

dresmaeili48@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-27, 1400/05/05

Expected recruitment end date

2022-07-27, 1401/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of anesthesia level of intrathecal injection after 1 and 1.5 cc bupivacaine 0.5% in saddle block

Public title

Comparison of anesthesia levels of intrathecal bupivacaine injection

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

class I & II of Anesthesia Society of America (ASA)

patients candidate for elective peri Anal surgery

Exclusion criteria:

Cardiovascular disease Chronic pain lung disease Opioids or alcohol dependency

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to two groups of 40 using 4 blocks and a ratio of 1: 1. The free website www.randomization.com will be used to generate the allocation sequence. The resulting sequence will be written on separate sheets and placed in sealed envelopes and will be provided to the lead researcher for study.

Blinding (investigator's opinion)

Not 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

Babol University of Medical Sciences, Gangafrooz Street, Daneshgah Square, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

471764136

Approval date

2021-06-15, 1400/03/25

Ethics committee reference number

IR.MUBABOL.REC.1400.152

Health conditions studied

1

Description of health condition studied

Sensory block level

ICD-10 code

T88.8

ICD-10 code description

Other specified complications of surgical and medical care, not elsewhere classified

Primary outcomes

1

Description

Level of sensory block

Timepoint

Every one minute until 15 minutes and then every 5 minutes until the end of block

Method of measurement

Use of alcohol contaminated cotton and niddle number 20

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: To create nerve block, 1 cc bupivacaine 0.5% (Abu Reihan Pharmacy) is injected once into the intrathecal space.

Category

Treatment - Drugs

2

Description

Intervention group: To create nerve block, 1.5 cc bupivacaine 0.5% (Abu Reihan Pharmacy) is injected once into the intrathecal space.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Mohammad Esmaeili

Street address

Ganjafrooz Avenue, Daneshgah Square, Ruhani

Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Reza Ghadimi
Street address
Vice-chancellor Of Research, Daneshgah Square,
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rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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
Babol University of Medical Sciences
Full name of responsible person
Mohammad Esmaeili
Position
Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is still no plan for its publish.

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