

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Clinical trial a comparison of sensory and motor block level between 0.5 vs 1cc Lidocaine 5% in saddle anesthesia for anorectal surgery

Protocol summary

Summary

Background & purpose : Saddle block is the method of choice for anorectal surgery. By increasing outpatient surgeries, attempts are carried out to substitute Lidocaine with other drugs or lowering its dose to decrease complications and rapid reversal of sensory and motor blocks. This study is designed to compare sensory and motor block level with 0.5 versus 1cc Lidocaine 5% in saddle block for anorectal surgery. Design of experiments: Single blind clinical trial Methods: Patients randomly divided into 50 ml Lidocaine 5% 1cc and 25 ml Lidocaine 5% 0.5cc groups. Inclusion criteria: 60 patients candidate for elective anorectal surgery at the age of 18-60 and set in class I & II of Anesthesia Society of America (ASA) was selected, Exclusion criteria: Patients with history of cardiovascular disease, psychologic, chronic pain, lung disease and opioids or alcohol dependency. Intervention: 1cc Lidocaine 5% for 30 patients and 0.5cc Lidocaine 5% for another 30 patients was injected in to intratecal space and both groups remained seated for 5 minutes and then they were placed in appropriate position for surgery. Main outcomes: Sensory block level, motor block level, pain, hemodynamic changes, nausea and vomiting .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201311196744N2**
Registration date: **2014-04-11, 1393/01/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-11, 1393/01/22

Registrant information

Name

Mehrafza Mir

Name of organization / entity

Babol university of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 8296

Email address

mmir46@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research, Babol University Of Medical Sciences

Expected recruitment start date

2012-08-01, 1391/05/11

Expected recruitment end date

2012-12-31, 1391/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial a comparison of sensory and motor block level between 0.5 vs 1cc Lidocaine 5% in saddle anesthesia for anorectal surgery

Public title

A comparison of sensory and motor block level between 0.5 vs 1cc Lidocaine 5% in saddle anesthesia for anorectal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criterion: patients candidate for elective

anorectal surgery set in class I & II of Anesthesia Society of America (ASA) was selected. Exclusion criteria: patients with history of cardiovascular disease, psychologic, chronic pain, lung disease and opioids or alcohol dependency.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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

2012-07-01, 1391/04/11

Ethics committee reference number

6446 /30/پ/ژ

Health conditions studied

1

Description of health condition studied

Post spinal blockade analgesia

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

2

Description

Level of motor block

Timepoint

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

Method of measurement

Ability to flex and extend thigh, knee, ankle

3

Description

Analgesia during surgery and after that

Timepoint

During surgery and 24 hours after that

Method of measurement

Pain score

Secondary outcomes

1

Description

Blood pressure

Timepoint

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

Method of measurement

Non- invasive manometer

2

Description

Heart rate

Timepoint

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

Method of measurement

Heat rate monitoring

3

Description

Nausea and vomiting

Timepoint

From begining to end of the block

Method of measurement

Observation and inquiry

Intervention groups

1

Description

Prevention group: Interatechal injection of 0.5 cc Lidocaine 5%

Category

Prevention

2

Description

Control group: Injection of 1 cc Lidocaine 5%

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Dr Mehrafza Mir

Street address

Shahid Ghasemi Avenue

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor Of Research Babol University Of Medical Sciences

Full name of responsible person

Dr Amrolah Mostafazadeh

Street address

Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

City

Babol

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

Contact

Name of organization / entity

Babol University Of Medical Sciences

Full name of responsible person

Dr Mehrafza Mir

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Phone

+98 11 1223 8296

Fax

Email

mmir46@yahoo.com; ans_dep@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University Of Medical Sciences

Full name of responsible person

Dr Mosataffa Faraji

Position

Resident of Anesthesiology

Other areas of specialty/work

Street address

Anesthesiology Department, Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Phone

+98 11 1223 8296

Fax

Email

mmir46@yahoo.com; ans_dep@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr Mehrafza Mir

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

Street address

Anesthesiology Department, Ruhani Hospital,
Daneshgah Square, Ganjafrooz Avenue

City

Babol

Postal code

Phone

+98 11 1223 8296

Fax

Email

mmir46@yahoo.com; ans_dep@yahoo.com

Web page address

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