Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial a comparision 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 Lidocaine5% 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 anorecctal 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 disase 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

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Babol university of Medical sciences
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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 comparision of sensory and motor block level between 0.5 vs 1cc Lidocaine 5% in saddle anesthesia for anorectal surgery

Public title

A comparision 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 disase 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/ژ/پ

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 conteminated 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
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Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue
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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
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
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Full name of responsible person
Dr Mehrafza Mir
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Other areas of specialty/work
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Person responsible for updating data

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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