

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparative study of Bupivacaine different doses in spinal anesthesia in anal surgeries

Protocol summary

Private

Summary

This is a randomized clinical trial which was done on two groups of 70 patients, with physical status ASA I or II, undergoing anorectal surgical procedures in Imam Reza Hospital, Kermanshah. They received 2mg 0.5% Bupivacaine or 5mg 0.5% Bupivacaine. Necessary time for anesthesia, peak block height by drug, recovery duration, patients' ambulation in recovery unit and operation duration were evaluated by examining the patient and filling out the Mc-Gill questionnaire.

Expected recruitment start date

2009-08-15, 1388/05/24

Expected recruitment end date

2010-02-15, 1388/11/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Scientific title

Comparative study of Bupivacaine different doses in spinal anesthesia in anal surgeries

Acronym

IRCT registration information

IRCT registration number: **IRCT138901213562N1**

Registration date: **2010-04-10, 1389/01/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-04-10, 1389/01/21

Registrant information

Name

Khosro Farhadi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1428 2670

Email address

kh-farhadi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Public title

Comparing different doses of Bupivacaine in spinal anesthesia in anal surgeries

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients who were candidate for elective anal surgeries with ASA I or II. Exclusion criteria: patients who had pain and did not answer to injecting 1cc of Fentanyl or the ones who their surgery took more than 15 min.

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Kermanshah university of medical sciences

Street address

#2 building, Shahid beheshti boulevard

City

Kermanshah

Postal code

67144-15333

Approval date

2009-08-15, 1388/05/24

Ethics committee reference number

2762/420/7p

Health conditions studied**1****Description of health condition studied**

spinal anesthesia

ICD-10 code

T80-T88

ICD-10 code description

complications of surgical and medical care, not elsewhere classified

Primary outcomes**1****Description**

pain degree

Timepoint

after performing spinal anesthesia and during surgery

Method of measurement

Mc-Gill questionnaire and VAS method

Secondary outcomes**1****Description**

ability to walk and finishing the block of S4 dermatom

Timepoint

after finishing the surgery

Method of measurement

VAS, clinician examination and direct interview with patient

Intervention groups**1****Description**

Group A: 2mg of Bupivacaine 0.5% hyperbaric was injected by 24 gague Quincke spinal needle in L4,L5 space in sitting position.

Category

Treatment - Drugs

2**Description**

Group B: 5mg of Bupivacaine 0.5% hyperbaric was injected by 24 gague Quincke spinal needle in L4,L5 space in sitting position.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Dr Khosro Farhadi

Street address

Parastar boulevard, Sorkhalijeh

City

Kermanshah

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Private

Full name of responsible person

Dr. Khosro Farhadi

Street address

Imam reza hospital, Parastar boulevard, Sorkhalijeh

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Private

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

67144-15333

Phone

+98 83 1428 2670

Fax**Email**

kh-farhadi@kums.ac.ir

Web page address**Person responsible for general inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Khosro Farhadi

Position

Anesthesiologist, assistant professor

Other areas of specialty/work**Street address**

Imam Reza Hospital, Parastar boulevard, Sorkhalijeh

City

Kermanshah

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Fax

+98 83 1428 2670

Email

kh-farhadi@kums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Khosro Farhadi

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Other areas of specialty/work**Street address**

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City

Kermanshah

Postal code**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