

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect Of adding Midazolam to Bupivacaine 0.5% On duration Of Spinal Anaesthesia In Inguinal Herniorrhaphy

Protocol summary

Study aim

The Effect of Intrathecal Midazolam on quality and duration of Spinal Anaesthesia in TURP

Design

In this double blind clinical trail 64 patients who will be scheduled for Inguinal Herniorrhaphy under Spinal Anesthesia(SA) in Velayat & Rajaei hospital of Qazvin will be randomly divided in 2 equal 32 patient group . 500 ml Ringer will be infused to patients. Standard monitoring will be started for patient. SA will be done in sitting position via L3-L4 space using disposable (G=26) needle. Following SA patient immediately turned to supine position Blinding: Patient, Anesthesiologist who do spinal anesthesia, and the Anesthesiologist who evaluate study outcomes are unaware about patients grouping.

Settings and conduct

In this Double blind clinical trail 64patients who will be scheduled for Inguinal Herniorrhaphy under Spinal Anesthesia in Velayat & Rajaei hospital of Qazvin will be randomly divided in 2 equal groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA I or II; male age 30–70 y Exclusion: drug abusers; motor sensory nerve disturbances; Diabete Mellitus; known sensitivity to study drugs used; spinal deformity or contraindication to SA

Intervention groups

Induction of spinal anesthesia will be done by using 10mg Bupivacaine plus 2 mg Midazolam in study group, and the same value of Bupivacaine plus 0.4ml 0.9% normal saline in control group (volume of drug will be reached to 2.4 ml in both group)

Main outcome variables

time of regression of sensory block & motor block to modified bromage scale 1. cardiovascular change during of anesthesia, and complication of block

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151223025676N9**

Registration date: **2018-12-23, 1397/10/02**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-23, 1397/10/02**

Update count: **0**

Registration date

2018-12-23, 1397/10/02

Registrant information

Name

Hamid Kayalha

Name of organization / entity

Qazvin University of Medical Sciences & Health Services

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 1007

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hkayalha@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of adding Midazolam to Bupivacaine 0.5% On

duration Of Spinal Anaesthesia In Inguinal Herniorrhaphy

Public title
The Effect Of adding Midazolam to Bupivacaine 0.5% On duration Of Spinal Anaesthesia In Inguinal Herniorrhaphy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
American Society of Anesthesiologists 1,2
Exclusion criteria:
Motor / sensory nerve disturbances Diabetes Mellitus known sensitivity to study drugs used, The Reluctance of patients Any other standard contraindication to spinal anesthesia Drug or Alcohol abusers

Age
From **30 years** old to **70 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization with WIN PEPI

Blinding (investigator's opinion)
Double blinded

Blinding description
Patient, Anesthesiologist who do spinal anesthesia, and the Anesthesiologist who evaluate study outcomes are unaware about patients grouping .

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Shahid Bahrani Blvd, Qazvin.
City
Qazvin.
Province
Qazvin

Postal code
3419759811
Approval date
2018-02-27, 1396/12/08
Ethics committee reference number
IR.QUMS.REC.1396.486

Health conditions studied

1

Description of health condition studied

Inguinal hernia

ICD-10 code

K40.9

ICD-10 code description

Unilateral or unspecified inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description

Time of regression of Sensory Block

Timepoint

Every 5 min in post anesthesia care unit

Method of measurement

Time need to regression of Sensory block to 2 lower dermatome level

2

Description

Time need to regression of Motor block

Timepoint

Every 5 min in post anesthesia care unit

Method of measurement

Based on Modified Bromage Scale

3

Description

First time of feeling pain

Timepoint

24 hours after surgery

Method of measurement

Score of Pain according to Visual Analog Scale

Secondary outcomes

1

Description

Cardiovascular change

Timepoint

every 5 min

Method of measurement

Using indirect Blood Pressure measurement & Heart rate via automated device

Intervention groups

1

Description

Intervention group: 10 Mg Bupivacaine 0.5% plus 2 mg Midazolam (total volume 2.2 ml)

Category

Treatment - Drugs

2

Description

Control group: 10Mg Bupivacaine 0.5% plus 0.2 MI 0.9% Normal Saline (total volume 2.2 MI)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat Educational and Treatment Center

Full name of responsible person

Dr. Mohamad Movahed

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Minoodar, 22 Bahman Blvd, Qazvin.

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2

Recruitment center

Name of recruitment center

Rajaii Educational and Treatment Center

Full name of responsible person

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Rajee Hospital, Padegan Avenu, Qzvin

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Sponsors / Funding sources

1

Sponsor

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Mohamad Movahed

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

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