Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intratechal bupivacaine versus intratechal meperdine on posr operative urinary retention in anorectal surgery

Protocol summary

Summary

After getting the approval of the local committee of ethics in Bushehr University of Medical Sciences, 78 patients whose age were 25 to 45 and are candidates for elective hemorrhoid surgery were randomly allocated into two groups. Control group received 5 mg standard bupivaqcaine 0.5%, intratechaly, Experimental group received 50 mg meperdine, intratechaly. Shivering, hemodynamic changes, nausea and vomiting, pain and urinary retention measured by the responsible nurse. The level of anesthesia in all four groups was: S2-S4.The site of needle insertion was T4-T5 by gauge number 24. The monitoring in the two groups were the same (NIBPM, Pulse oximetry, heart rate in minutes: 1, 3, 10, 20, 30, 60 and in recovery room. Shivering was classified as CROOSLY described. Urinary retention grade were: 0=none, 1=hesitancy, 2=strait catheter required and 4=foly catheter required

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110201936N7**
Registration date: **2011-11-08, 1390/08/17**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-11-08, 1390/08/17

Registrant information

Name
Abdolreza Najafi Anaraki
Name of organization / entity
Bushehr University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Bushehr University of Medical Sciences

Expected recruitment start date

2011-12-01, 1390/09/10

Expected recruitment end date

2012-05-15, 1391/02/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intratechal bupivacaine versus intratechal meperdine on posr operative urinary retention in anorectal surgery

Public title

The effect of intratechal bupivacaine versus intratechal meperdine on posr operative urinary retention in anorectal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The patients' age between 25 to 45 and being candidate for hemorrhoid surgery (grade 11 - GRADE1V). Exclusion criteria: diabetes mellitus; history of urinary obstruction, major trauma of pelvis and any sign of neurological bladder

Age

From **25 years** old to **45 years** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Bushehr University of Medical Sciences
Street address
Bushehr-siraf avenue
City
Bushehr
Postal code
Approval date
2011-10-20, 1390/07/28
Ethics committee reference number
B-90-13-8

Health conditions studied

1

Description of health condition studied
Post operative urinary retention
ICD-10 code
N32.9
ICD-10 code description
Bladder disorder, unspecified

Primary outcomes

1

Description
Post operative urinary retention
Timepoint
Six hours after surgery
Method of measurement
Observation

Secondary outcomes

1

Description
Pain Score
Timepoint
Till 12 hours after surgery
Method of measurement
Observation

Intervention groups

1

Description
Control group receive 5 mg of bupivacaine, Bupivacaine is a mide local anesthetic and will be injected once intrathecally in concentratioin of 0.5% before surgery
Category
Treatment - Drugs

2

Description
Intervention group receive 50 mg of meperdine. Meperdine is an opioid with some local anesthetic effect and will be injected once intrathecally in dose of 50 mg equals to one milliliter before surgery
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fateme Zahra hospital
Full name of responsible person
Dr. Najafianaraki
Street address
City
Bushehr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bushehr University of Medical Sciences
Full name of responsible person
Dr. Afshin Ostovar
Street address
Siraf avenue
City
Bushehr
Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bushehr 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

Bushehr University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

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Street address

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City

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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