Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of post Operative analgesia with intraoperative administration of bupivacaine localy and intrersphincteric in hemorrhoidectomy operation

Protocol summary

Study aim
Comparison of analgesia after hemorrhoidectomy using local and intrasphincteric injection of bupivacaine

Design
This is a double-blind clinical trial study with parallel groups that is performed by simple randomization method with the help of STATA software on 60 patients referred for hemorrhoidectomy.

Settings and conduct
All patients referred to hospitals and private clinics for hemorrhoidectomy who met the inclusion and exclusion criteria were included in the study. After performing a similar anesthesia procedure, one group underwent local injection and the other group underwent intrasphincteric injection in 4 positions (12, 3, 6, and 9 o'clock). Finally, hemorrhoidectomy is performed. Finally, 6 and 12 hours after Patients' full recovery, the patient's need for analgesia, and pain intensity are assessed and compared using a Visual Analogue Scale for Pain that will be used for both groups. The patient and the person evaluating the pain are blind to the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria were people between the ages of 20 and 70 and those who were in Class I and II according to the ASA (anesthesia class) criteria, and the non-inclusion criteria were those who were in Class III and IV according to the ASA criteria. People with a history of drug addiction, people with a history of any heart, liver, kidney or neurological disease, or allergies to any medication, and inability to determine the use of a verbal scale.

Intervention groups
In patients referred for hemorrhoidectomy, bupivacaine injection is performed to reduce postoperative pain at the operation site by two methods, local and intrasphincteric, and finally Postoperative analgesia is compared.

Main outcome variables
Evaluation patients' pain after surgery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201031049201N1**
Registration date: **2020-11-12, 1399/08/22**
Registration timing: **prospective**

Last update: **2020-11-12, 1399/08/22**
Update count: **0**

Registration date
2020-11-12, 1399/08/22

Registrant information

Name
Seyed Sana Davoudi Moghadam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 54 3329 5770

Email address
sana.davoudi@zaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-15, 1399/08/25

Expected recruitment end date
2021-05-21, 1400/02/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of post Operative analgesia with intraoperative administration of bupivacaine localy and intrersphincteric in hemorrhoidectomy operation

Public title

Comparison of the effect of anesthetic injection in two ways on pain in patients after hemorrhoidectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

People between the ages of 20 and 70 People who met the ASA criteria (anesthesia class)in class I and II

Exclusion criteria:

People with a history of drug addiction People with a history of any heart, liver, kidney, neurological disease Allergies to any medication Inability to determine the use of verbal pain scale (such as people with mental disabilities) Dissatisfaction with participation in the study

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization is used and the unit is individual randomization. In this way, with the help of STATA software, random codes are assigned to each patient in both intervention groups about the injection method and are recorded on a questionnaire, and the patient and the questioner are blind to avoid bias towards those codes.

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining the patient's informed consent, surgery is performed and the patient does not know about his anesthesia method during the operation. Also, after the operation and the patient entering the ward, the questioner does not know about the injection method and only completes the pain questionnaire.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan, Dr hesabi Square, Pardis of medical sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2020-01-05, 1398/10/15

Ethics committee reference number

IR.ZAUMS.REC.1399.318

Health conditions studied

1

Description of health condition studied

Hemorrhoid

ICD-10 code

K64.8

ICD-10 code description

Other hemorrhoids

Primary outcomes

1

Description

Pain status after hemorrhoidectomy in both groups

Timepoint

Evaluation of pain status in both groups 6 and 12 hours after surgery

Method of measurement

Visual Analogue Scale for patient that is measured by the patient from 0 to 10

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: All patients received 1 gram of antibiotic (keflin) before the operation and by the same method of general anesthesia, by receiving 5 cc per kg

of preloaded fluid and then by injecting 1-2 micro grams per kilogram of fentanyl and 1-2 Mg per kg succinylcholine and 3-5 mg per kg Nestonal are anesthetized. Then, in the lithotomy position, one group underwent intra-sphincter injection of bupivacaine by Abu Reihan company in 4 positions (12, 3, 6, 9 and 9 o'clock).

Category

Prevention

2

Description

Intervention group: The second intervention group underwent local bupivacaine injection at the site of lithotomy with a similar anesthesia method.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Research Hospital

Full name of responsible person

Seyed Sana Davoudi Moghadam

Street address

Salamat Blvd, Persian Gulf highway, Imam Ali Research Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Seyed Mohammad Nasiruddin Tabatabai

Street address

Dr Hesabi Square, Pardis of medical science

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Seyed Sana Davoudi Moghadam

Position

Resident of surgery

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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Position

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Person responsible for updating data

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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