

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of the success rate of spinal anesthesia with lidocaine and spinal anesthesia with meperidine in anal fissure surgery.

Protocol summary

Study aim

Comparison of the success rate of spinal anesthesia with lidocaine and spinal anesthesia with meperidine in anal fissure surgery

Design

Clinical trial with control and control groups, double-blind, randomized, phase 3 on 138 patients

Settings and conduct

After referring to Ayatollah Kashani Hospital in Isfahan and Hazrat Ali Asghar (AS) Noro Hospital and checking the operation conditions, the samples are entered into the study and then they are randomly (by SPSS software) into two groups for anesthesia. They are divided into preoperative spinal anesthesia with lidocaine or spinal anesthesia with meperidine. This is a two-blind study in which the patient is unaware of the assigned group and also the surgeon who measures and evaluates the results of the intervention is unaware of the assigned group.

Participants/Inclusion and exclusion criteria

all of patient with chronic anal fissure

Intervention groups

group 1:anal fissure surgery with spinal anesthesia with meperidine group2:anal fissure surgery with spinal anesthesia with lidocain

Main outcome variables

Intraoperative sphincter tone in Fisher Anal surgery:
Postoperative analgesia: Effects of lidocaine and meperidine on the central nervous system and different side effects of these two drugs in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180921041078N1**

Registration date: **2020-12-26, 1399/10/06**

Registration timing: **retrospective**

Last update: **2020-12-26, 1399/10/06**

Update count: **0**

Registration date

2020-12-26, 1399/10/06

Registrant information

Name

Ali Rezaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3265 4563

Email address

ali_medi_84@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-24, 1397/06/02

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

2018-08-23, 1397/06/01

Actual recruitment end date

2020-08-22, 1399/06/01

Trial completion date

2020-08-22, 1399/06/01

Scientific title

Comparison of the success rate of spinal anesthesia with lidocaine and spinal anesthesia with meperidine in anal fissure surgery.

Public title

effectiveness between lidocain and meperidin in anal fissure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
all patients with anal fissure

Exclusion criteria:
Patient dissatisfaction with spinal anesthesia infection site of spinal anesthesia coagulopathy

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **120**
Actual sample size reached: **138**

Randomization (investigator's opinion)
Randomized

Randomization description
The anesthesiologist performs spinal anesthesia with lidocaine and pethidine as one of the patients, and the surgeon does not know how the drug is used in spinal anesthesia. Also a surgical nurse who does not know how to operate (blind sampling)

Blinding (investigator's opinion)
Double blinded

Blinding description
lack of patients awareness lack of surgeon awareness to plan of spinal anesthesia

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Sofe ave ,Alzahra hospital,Isfahan town (General surgeon official)

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2018-08-11, 1397/05/20

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.105

Health conditions studied

1

Description of health condition studied

chronic anal fissure

ICD-10 code

K60.1

ICD-10 code description

Chronic anal fissure

Primary outcomes

1

Description

sphincter tone in spinal anesthesia with meperidine compared to spinal anesthesia with lidocaine

Timepoint

During the anal fissure surgery

Method of measurement

Anal manometry

2

Description

Comparison of mean pain score in 2 hours. 4, 6, 12 and 24 after surgery based on NSR questionnaire in spinal anesthesia with lidocaine and meperidine

Timepoint

after surgery

Method of measurement

NSR questionnaire

3

Description

Comparison of the frequency distribution of lidocaine-induced complications with meperidine-induced complications during and after surgery in two methods of spinal anesthesia with lidocaine and spinal anesthesia with meperidine

Timepoint

During and after surgery

Method of measurement

NSR questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient is placed in a sitting position after rinsing the back with betadine solution of 24-gauge Quinke spinal needle No. 24 (24-gauge Quinke spinal needle) enters the intrathecal space between the fourth and fifth lumbar vertebrae and after confirming the intrathecal space with fluid out The spinal cord is

used from the end of a 25 mg pethidine needle. The patient remains seated for 5 minutes and then the patient is placed in a suitable position (lithotomy) to perform the relevant operation.

Category

Treatment - Drugs

2

Description

Control group: The patient is placed in a sitting position after washing the back with betadine solution of 24-gauge Quinke spinal needle No. 24 (24-gauge Quinke spinal needle) enters the intrathecal space between the fourth and fifth lumbar vertebrae and after confirming the intrathecal space with fluid exit Spinal cord From the end of the needle of lidocaine drug 0.5 ml of 5% lidocaine is used. The patient remains seated for 5 minutes and then the patient is placed in a suitable position (lithotomy) to perform the relevant operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital

Full name of responsible person

Safae Masome MD (SURGEON)

Street address

KASHANI AVE .KASHANI HOSPITAL. ISFAHAN

City

ISFAHAN

Province

Isfahan

Postal code

51839-83434

Phone

+98 31 3223 0091

Fax

Email

ali_medi_84@yahoo.com

Web page address

2

Recruitment center

Name of recruitment center

Khorshid Hospital

Full name of responsible person

Safae Masome MD (SURGEON)

Street address

Ostandari Ave.Isfahan town

City

Isfahan

Province

Isfahan

Postal code

81839-83434

Phone

+98 31 3222 2127

Email

ali_medi_84@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Yosof Gheysari MD

Street address

Sofe Ave ,Isfahan univercity,Isfahan town

City

Isfahan

Province

Isfahan

Postal code

8117467341

Phone

+98 31 3793 2171

Email

research.deputy@dean.ui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Research and Technology Official

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

Esfahan University of Medical Sciences

Full name of responsible person

Ali Rezaee

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

General surgeon official,Alzahra hospital,Isfahan town

City

Isfahan

Province
Isfahan
Postal code
8174675731
Phone
+98 31 1668 5555
Email
ali_medi_84@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Safae Masome MD
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
General surgeon official, Alzahra hospital, Isfahan town
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 1668 5555
Fax
Email
safae.masumeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Ali Rezaee
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
General surgeon official, Alzahra hospital, Isfahan town
City
Isfahan
Province
Isfahan
Postal code
8174675731
Phone
+98 31 1668 5555
Email
ali_medi_84@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Final incompleteness

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available