

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Compare the effect of subcutaneous injection of ketamine and lidocaine in reducing postoperative pain in patients undergoing elective inguinal hernia surgery under general anesthesia

Protocol summary

Study aim

Comparison of the effect of subcutaneous injection of ketamine and lidocaine on reducing postoperative pain in patients undergoing elective inguinal hernia surgery under general anesthesia.

Design

In this research, 60 eligible patients referring to inguinal hernia Association were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two intervention groups and one control group.

Settings and conduct

Place: Hospital 5th Azar Gorgan Hospital After surgery, after peritoneal closure, 0.5 mg / kg of ketamine is injected into the 10 cc volume and then injected. In the lidocaine group, it also injects 1mg / kg into 10cc and then injects. In the control group, the surgical site is not injected.

Participants/Inclusion and exclusion criteria

A total of 60 candidates for elective inguinal hernia surgery under general anesthesia with ASA class 1 and 2 were randomly divided into subcutaneous chitin and subcutaneous lidocaine subgroups and control group. The person evaluating the pain and the drug injector will not know the contents of the injected syringe. The criteria for entering the study include the age of the patient between the ages of 18 and 60. Exclusion criteria include hypertension, hyperthyroidism, history of seizure, nervous and psychiatric disorders, signs of increased intracranial pressure, ketamine or lidocaine allergy, liver and kidney failure, substance abuse or alcohol abuse (patient dissatisfaction, coagulation disorder - local infections Location - Neurological disorders - Severe anemia).

Intervention groups

1. The subcutaneous injection of lidocaine in the surgical site
2. The subcutaneous injection of ketamine in the

surgical site 3. Control group without subcutaneous injection at the surgical site

Main outcome variables

Reducing pain in the surgical cutting site

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171004036561N3**

Registration date: **2018-02-10, 1396/11/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-10, 1396/11/21**

Update count: **0**

Registration date

2018-02-10, 1396/11/21

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3254 2414

Email address

masoud.hoseini@webmail.goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of subcutaneous injection of ketamine and lidocaine in reducing postoperative pain in patients undergoing elective inguinal hernia surgery under general anesthesia

Public title

Compare the effect of subcutaneous injection of ketamine and lidocaine in reducing postoperative pain in patients undergoing elective inguinal hernia surgery under general anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing elective inguinal hernia surgery under general anesthesia

Exclusion criteria:

Hypertension Hyperthyroidism History of seizure Nervous and mental illness Symptoms of increased intracranial pressure Ketamine or lidocaine allergy Liver and kidney failure Substance abuse or alcohol abuse Patient dissatisfaction Coagulation disorders Localized local infections Neurological disorders Sever Anemia

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Blocks (six blocks)

Blinding (investigator's opinion)

Double blinded

Blinding description

The first follow up is done in recovery and the recovery nurse and the operating room are different, for this reason the first investigator is blind and the second investigator is the nurse in the surgical department and do not know the type of the drug in the operating room, and blindness has been done.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Golestan University of Medical Sciences

Street address

5 Azar Hospital, 5 Azar Blvd, Gorgan

City

Gorgan

Province

Golestan

Postal code

4917761551

Approval date

2017-09-05, 1396/06/14

Ethics committee reference number

IR.GOUMS.REC.1396.129

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

Inguinal Hernia

ICD-10 code

K40.9

ICD-10 code description

Unilateral inguinal hernia, without obstruction or gangrene

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

Percent reduction in pain

Timepoint

1, 2, 4, 6 and 8 Hours after general anesthesia

Method of measurement

Visual analogue scale

Secondary outcomes

empty

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

Intervention group 1: Subcutaneous injection of 1mg/kg lidocaine in the surgical cutting site

Category

Treatment - Drugs

2

Description

Intervention group 2: Subcutaneous injection of 0/5mg/kg ketamin in the surgical cutting site

Category

Treatment - Drugs

3

Description

Control group: Lack of subcutaneous injection of the drug in the surgical cutting site

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar Hosaital

Full name of responsible person

Seyyed Massoud Hosseini

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Dr.masoud.hoseynee@gmail.com

Web page address

http://www.goums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gorgan University of Medical Sciences

Full name of responsible person

Mohammad Reza Honarvar

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5 Azar Hospital - Gorgan

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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

Gorgan 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

Gorgan University of Medical Sciences

Full name of responsible person

Seyyed Massoud Hosseini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is unobtrusive when unrecognizable

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

all

Under which criteria data/document could be used

There is no specific condition and the data will be publicly available

From where data/document is obtainable

Dr.Masoud.hoseynee@Gmail.Com

What processes are involved for a request to access data/document

Send an email

Comments