Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Aazar 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 Hosoital
Full name of responsible person
Seyyed Massoud Hosseini
Street address
5 Azar Hospital، 5 Azar Blvd، Gorgan
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Golestan
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4917761551
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Email
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
Street address
5´Azar Hospital - Gorgan
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Dr.masoud.hseynee@Gmail.com
Web page address
http://www.goums.ac.ir
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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Golestan university of medical Ssciences، Basij square، Gorgan
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
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Latest degree
Medical doctor
Other areas of specialty/work
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Postal code
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Phone
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Email
masoud.hoseini@webmail.goums.ac.ir

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