Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The effect of subcutaneous injection of metoclopramide, pethidine and ketamine on the postoperative pain after inguinal hernia repair under general anesthesia

Protocol summary

Study aim

To investigate the effect of subcutaneous injection of metoclopramide, pethidine or ketamine on preventing the postoperative pain after inguinal hernia repair under general anesthesia compared to the control group.

Design

Randomized, triple-blinded, controlled and preventive clinical trial with a parallel group design of 104 patients.

Settings and conduct

This clinical trial, will be carried out in Alzahra Hospital, Isfahan, in order to assess and compare the effect of ketamine, pethidine and metoclopramide subcutaneous administration at the incision site, compared to the control group(normal saline) for prevention of pain after inguinal hernia repair surgery. 104 patients will be selected and randomly divided into four groups of 26 patients. Their pain using VAS score, the hemodynamic parameters, extubation and recovery time, drug complications, total rescue analgesic consumption, time to first analgesic request and satisfaction score will be evaluated within the first 24 hours after surgery. the patients, the person injecting the drug, and the person analyzing the data will be unaware of the type of the drugs.

Participants/Inclusion and exclusion criteria

The patients with ages of 18-65 years old and an ASA class I-II who are candidates for elective inguinal hernia repair under general anesthesia will be included in our study. Exclusion criteria will include uncontrolled systemic diseases, history of chronic pains in the previous 6 months and any analgesic consumption in the previous 24 hours.

Intervention groups

The patients will receive subcutaneous injection at the incision site, based on their grouping code: 1) 0.5 mg/kg Ketamine; 2) 0.75 mg/kg Petidine; 3) 0.1 mg/kg Metoclopramide & 4) Normal saline.

Main outcome variables

The pain intensity using VAS score within the first 24 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150106020588N7**
Registration date: **2020-05-26, 1399/03/06**
Registration timing: **retrospective**

Last update: **2020-05-26, 1399/03/06**
Update count: **0**

Registration date

2020-05-26, 1399/03/06

Registrant information

Name

Darioush Moradi Farsani

Name of organization / entity

Isfahan Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

2018-04-04, 1397/01/15

Actual recruitment end date

2018-08-06, 1397/05/15

Trial completion date

2018-08-07, 1397/05/16

Scientific title

The effect of subcutaneous injection of metoclopramide, pethidine and ketamine on the postoperative pain after inguinal hernia repair under general anesthesia

Public title

effect of metoclopramide, pethidine and ketamine on the postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

The patients with ASA(American Society of Anesthesiologists) class I-II who are undergoing elective inguinal hernia repair under general anesthesia

Exclusion criteria:

Uncontrolled systemic diseases Drug sensitivity to pethidine, metoclopramide and ketamine History of opium or alcohol addiction History of chronic pains in previous 6 months Any analgesic consumption in previous 24 hours History of Hypertension, Hyperthyroidism and psycologic disorders

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **104**

Actual sample size reached: **104**

Randomization (investigator's opinion)

Randomized

Randomization description

104 patients are needed for this study, 26 in each of the four groups. We will prepare 104 envelopes, containing either number 1, 2, 3, or 4. The envelopes will be shuffled randomly. The envelopes will be then handed out for each patient to an anesthesiologist. The anesthesiologist will then apply the subcutaneous injections based on the code in the envelopes.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patients are unaware of what group they are assigned to, and the drug used. Drugs were prepared in the same and coded syringes by one of the anesthesiology specialists who are not in the study. In addition, the person assessing the outcome is different from the person who performs the injection of drugs and they are not aware of the type of drug injected to the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of School of Medicine - Isfahan University of Medical Sciences

Street address

Hezar Jarib St.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2017-10-23, 1396/08/01

Ethics committee reference number

IR.MUI.REC.1396.3.609

Health conditions studied

1

Description of health condition studied

Inguinal Hernia

ICD-10 code

K40

ICD-10 code description

Inguinal hernia

2

Description of health condition studied

Surgical Incision Pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Local pain in the incision site of the surgery

Timepoint

Within the initial 24 hours after the surgical repairing of inguinal hernia

Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Overall satisfaction of patients
Timepoint
24 hours after the surgery
Method of measurement
Lickert scale from 1 to 5

Intervention groups

1

Description
First intervention group: in this group, 0.5 mg/kg of ketamine produced by Abidi company, which will be added to normal saline up to volume of 10 ml, will be injected subcutaneously at the icision site right before the closure of skin.
Category
Treatment - Drugs

2

Description
Second intervention group: in this group, 0.75 mg/kg of pethidine produced by Abidi company, which will be added to normal saline up to volume of 10 ml, will be injected subcutaneously at the incision site right before the closure of skin.
Category
Treatment - Drugs

3

Description
Third intervention group: in this group, 0.1 mg/kg of metoclopramide produced by Abidi company, which will be added to normal saline up to volume of 10 ml, will be injected subcutaneously at the incision site right before the closure of skin.
Category
Treatment - Drugs

4

Description
Control group: in this group, 10 ml of normal saline solution produced by Abidi company, will be injected subcutaneously at the incision site right before the closure of skin.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Darioush Moradi Farsani
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Sponsors / Funding sources

1

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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
Esfahan University of Medical Sciences
Proportion provided by this source
50
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
Zahra Azamian

Position
Assistant

Latest degree
Medical doctor

Other areas of specialty/work
Cardiology

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Web page address

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
Due to shortage of time that we have, we are not able to make any amendments or promises that we can share the output.

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