

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

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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
 Isfahan
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 incision 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****Sponsor****Name of organization / entity**

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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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Assistant Professor of Anesthesiology and critical care

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Specialist

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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