

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of Ketorolac and Paracetamol on Pain Control after Inguinal Hernia Surgery

Protocol summary

Summary

(1) Objective: Determining the effect of Ketorolac and Paracetamol on pain control after inguinal hernia surgery. (2) Design: Double blind clinical trial study (3) Setting and conduct: Selecting 74 patients under elective inguinal hernia surgery at 5Azar tertiary hospital affiliated to Golestan university of medical sciences and assigning them to two intervention groups by simple random allocation. (4) Participants including major eligibility criteria: Inclusion Criteria: age between 20 to 50 years; American Society of Anesthesiologists (ASA) physical status classification system I and II; without chronic and psychologic diseases; no addiction to substance; Under general anesthesia and inducing anesthesia by Fentanyl (1 mcg/ kg), Sodium Thiopental (5 mg/ kg), and Atracurium (0.5 mg/ kg) and maintain it by nitrous oxide (N2O) and Izoflurane; and filling the informed consent form. Exclusion Criteria: needing to administration of extra dosage of drug, another drug; or alternative therapy. (5) Intervention: Injection of Paracetamol (15 mg/ kg every 6 hours, maximal dosage of 60 mg/ kg, daily) for the first group, and injection of Ketorolac (maximal dosage of 120 mg, daily) for the second intervention group after one hour after Fentanyl injection. (6) Main outcome measures (variable): Pain after inguinal hernia surgery for two intervention groups for 6 hours after Ketorolac and Paracetamol injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041033350N1**
Registration date: **2017-05-04, 1396/02/14**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-04, 1396/02/14

Registrant information

Name

Ali Mahmoud Janlou

Name of organization / entity

Golestan university of Medical Sciences, Gorgan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 17 3235 4936

Email address

mahmoud.janlou@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Golestan University of Medical Sciences, Gorgan, Iran

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2017-07-06, 1396/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Ketorolac and Paracetamol on Pain Control after Inguinal Hernia Surgery

Public title

Effect of Ketorolac and Paracetamol on Pain Control after Hernia Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: age between 20 to 50 years; American Society of Anesthesiologists (ASA) physical status classification system I and II; without chronic and psychologic diseases; no addiction to substance; Under general anesthesia and inducing anesthesia by Fentanyl (1 mcg/ kg), Sodium Thiopental (5 mg/ kg), and Atracurium (0.5 mg/ kg) and maintain it by nitrous oxide (N2O) and Izoflurane; and filling the informed consent form. Exclusion Criteria: needing to administration of extra dosage of drug, another drug; or alternative therapy.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not 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

Postal code: 4934174515, beginning of the Shastkola road, Falsafi educational campus, Gorgan, Golestan province, Iran.

City

Gorgan

Postal code

4934174515

Approval date

2017-02-12, 1395/11/24

Ethics committee reference number

IR.GOUMS.REC.1395.241

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

inguinal hernia surgery

ICD-10 code

k40

ICD-10 code description

inguinal hernia

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

Pain after inguinal hernia surgery

Timepoint

6 hours after injection of Paracetamol and Ketorolac during time period of 1 hour, every half an hour for 2 hours, and every one hour for 3 hours.

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

empty

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

First intervention group: Injection of Paracetamol (15 mg/ kg every 6 hours, maximal dosage of 60 mg/ kg, daily) one hour after Fentanyl injection.

Category

Treatment - Drugs

2**Description**

Second intervention group: injection of Ketorolac (maximal dosage of 120 mg, daily) one hour after Fentanyl injection.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

5 Azar tertiary hospital affiliated to Golestan University of Medical Sciences

Full name of responsible person

Dr. Ali Mahmoud janloo

Street address

5th Azar street, 5 Azar tertiary hospital, Gorgan, Golestan province, Iran.

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Golestan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Taziki

Street address

Postal code: 4934174515, beginning of the Shastkola road, Falsafi educational campus, Gorgan, Golestan province, Iran.

City

Gorgan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Golestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Golestan University of Medical Sciences

Full name of responsible person

Dr. Ali Mahmoud Janlou

Position

Anesthesiology resident

Other areas of specialty/work**Street address**

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Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Golestan University of Medical Sciences

Full name of responsible person

Dr. Araz Berdi Qurchai

Position

anesthesiologist

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Person responsible for updating data

Contact**Name of organization / entity**

Golestan University of Medical Sciences

Full name of responsible person

Dr. Ali Mahmoud Janlou

Position

Anesthesiology resident

Other areas of specialty/work**Street address**

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty