

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the prophylactic effectiveness of intravenous Ibuprofen and intramuscular Piroxicam on pain intensity after lower abdominal surgery under general anesthesia

Protocol summary

Study aim

Comparison of the prophylactic effectiveness of intravenous Ibuprofen and intramuscular Piroxicam on pain intensity after lower abdominal surgery under general anesthesia

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients. Random allocation software is used for randomization.

Settings and conduct

Immediately after induction of anesthesia and before surgical incision, in the Piroxicam group, 20 milligrams (mg) of intramuscular Piroxicam, in the Ibuprofen group, 400 mg of Ibuprofen and in the control group, intravenous Normal saline is injected and then, at certain hours after surgery, its effect on reducing postoperative pain is compared in three groups. This study is performed in Al-Zahra Hospital in Isfahan. Patients and researcher are not aware of the type of injected drugs.

Participants/Inclusion and exclusion criteria

Class 1 and 2 patients in the American society of Anesthesiology (ASA) classification system aged 25 to 65 years that candidates for lower abdominal surgery without history of drugs, alcohol and benzodiazepine addiction, without history of seizures, psychiatric problems, liver and kidney disease, gastrointestinal bleeding, peptic ulcer and Coagulation disorder No allergy to the drugs used in the study

Intervention groups

In the Piroxicam group, 20 milligrams (mg) of intramuscular Piroxicam, in the Ibuprofen group, 400 mg of Ibuprofen and in the control group, intravenous Normal saline is injected into each patient.

Main outcome variables

Postoperative pain intensity; Average opioids consumption in the first 24 hours after surgery; Mean heart rate and blood pressure during surgery; First time

of requesting opioids; Duration of stay in recovery; extubation time; Degree of patient satisfaction with pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210331050801N1**

Registration date: **2021-07-12, 1400/04/21**

Registration timing: **prospective**

Last update: **2021-07-12, 1400/04/21**

Update count: **0**

Registration date

2021-07-12, 1400/04/21

Registrant information

Name

Zahra Amouaghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3529 1723

Email address

zr.amouaghaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-01, 1400/05/10

Expected recruitment end date

2021-09-01, 1400/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the prophylactic effectiveness of intravenous Ibuprofen and intramuscular Piroxicam on pain intensity after lower abdominal surgery under general anesthesia

Public title

Comparison of the effect of Ibuprofen and Piroxicam on pain relief after surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

ASA1 and ASA2 patient Patient aged 25 to 65 years
Patients undergoing lower abdominal surgery No history of drugs, alcohol and benzodiazepine addiction No history of seizures, psychiatric problems, liver and kidney disease, gastrointestinal bleeding, peptic ulcer and Coagulation disorder No allergy to the drugs used in the study

Exclusion criteria:**Age**From **25 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, block randomization method is used. Patients who have the inclusion criteria are selected sequentially so that the first 3 are considered as a block and Then, using random allocation software, they are randomly divided into 3 groups: ibuprofen, piroxicam and control. This process continues until 90 patients enter the study. Thus, we will have equally 30 patients in each group (ibuprofen, piroxicam and control).

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants in study are unaware of the type of drug being injected. An anesthesiologist, who has no role in data collecting, prepares the medication in same volume and injects them. The data collector and the person who evaluating the outcome are not aware of the grouping of patients and the type of injected drug But the data analyzer is informed.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan university of medical sciences

Street address

Hezar jarib Ave, Azadi Square

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Approval date

2020-07-11, 1399/04/21

Ethics committee reference number

IR.MUI.MED.REC.1399.286

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

Postoperative pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

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

Intensity of postoperative pain

Timepoint

Immediately after consciousness in recovery and 2, 8, 12 and 24 hours after surgery

Method of measurement

visual analogue scale

2**Description**

The amount of opioid used in the first 24 hours after surgery

Timepoint

First 24 hours after surgery

Method of measurement

Reading the patient file

3

Description

Blood pressure

Timepoint

At the beginning of surgery and then every 30 minutes during surgery

Method of measurement

Digital barometer

4

Description

Heart rate

Timepoint

At the beginning of surgery and then every 30 minutes during surgery

Method of measurement

Pulse oximeter

5

Description

Duration of stay in recovery

Timepoint

After leaving the recovery

Method of measurement

Minute

6

Description

Extubation time

Timepoint

After extubation

Method of measurement

Minute

7

Description

The first time of requesting opioid after surgery

Timepoint

After end of surgery

Method of measurement

Minute

8

Description

Degree of patients' satisfaction with pain relief

Timepoint

24 hours after surgery

Method of measurement

Use of visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Immediately after induction of anesthesia (which is the same in all 3 groups) and before surgical incision, 20 mg Piroxicam (made by Alborz daroo factory) is injected intramuscularly into patient who is going to have lower abdominal surgery.

Category

Prevention

2

Description

Intervention group: Immediately after induction of anesthesia (which is the same in all 3 groups) and before surgical incision, 400 mg Ibuprofen (made by Caspian factory) is injected intravenously into patient who is going to have lower abdominal surgery.

Category

Prevention

3

Description

Control group: Immediately after induction of anesthesia (which is the same in all 3 groups) and before surgical incision, Normal saline serum (With a volume equal to the other two group`s drug) is injected intravenously into patient who is going to have lower abdominal surgery.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Al-Zahra Hospital

Full name of responsible person

Gholamreza Khalili

Street address

Al-Zahra Hospital, Sofe Blvd.

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khalili@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo Javanmard

Street address

Vice chancellor or research and technology, Isfahan
University of Medical Sciences, Hezar jarib Ave.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Khalili

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

all of data is potentially shareable after unidentifying individuals.

When the data will become available and for how long

Access period starts 6 months after the results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

use in other studies

From where data/document is obtainable

khalili@med.mui.ac.ir

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

After sending email, the request is read and reviewed and then will be answered as soon as possible.

Comments