

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Preemptive comparative study of the effect of Apotel and intravenous Ketorolac on pain after laparoscopic cholecystectomy surgery under general anesthesia

Protocol summary

Study aim

1. Reducing the use of systemic narcotics
2. Reducing the side effects of systemic narcotics following their use
3. Early discharge of the patient from the hospital and reduction of the length of hospitalization
4. Increasing satisfaction of patient and recovery staff by reducing postoperative pain

Design

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

Settings and conduct

This study is a randomized, triple-blind clinical trial (patient, data collector, and statistical consultant who performs statistical analysis don't know anything about groups in this study) on 90 patients aged 18-65 years with ASA class one and two who Cholecystectomy is performed on them under general anesthesia.

Demographic and physiological information of patients are recorded by using pre-prepared information forms. Patients are divided into 3 groups by using random allocation software.

Participants/Inclusion and exclusion criteria

Candidate patients aged 18-65 for laparoscopic cholecystectomy under general anesthesia with ASA class 1 and 2 Addiction, underlying diseases, previous allergies to drugs

Intervention groups

Patients are divided into 3 groups by using random allocation software. Group A receives 30mg intravenous ketorolac in 50cc normal saline, group B receives 2gr Apotel in 50cc normal saline and group C as a control group receives 50cc normal saline before general anesthesia and 30minutes before surgical incision .

Main outcome variables

by reducing the post operative pain , sympathetic stimulation and risk of cardiovascular disorder and post

operative narcotic use will be reduced.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101211005362N30**

Registration date: **2022-04-26, 1401/02/06**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-26, 1401/02/06**

Update count: **0**

Registration date

2022-04-26, 1401/02/06

Registrant information

Name

Mohammadreza Safavi

Name of organization / entity

Anesthesiology and Critical Care Research Center,
Isfahan University of Medical Sciences, Isfahan

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-19, 1400/12/28

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preemptive comparative study of the effect of Apotel and intravenous Ketorolac on pain after laparoscopic cholecystectomy surgery under general anesthesia

Public title

The effect of Apotel and Ketorolac on pain after surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate patients aged 18-65 years for laparoscopic cholecystectomy under general anesthesia with ASA class 1 and 2

Exclusion criteria:

addiction underlying disease drug allergy

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study simple randomization is done and patients are divided into 3 groups (A,B,C) by using random allocation software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a randomized, triple-blind clinical trial in which the patient and the person collecting the data and the statistical consultant performing the statistical analysis have no knowledge of the groups in this study .

Placebo

Not 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

Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2022-01-18, 1400/10/28

Ethics committee reference number

IR.MUI.MED.REC.1400.749

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

Pain after laparoscopic cholecystectomy

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

VAS

Timepoint

Visual Analogue Scale is assessed at 1, 2, 3, 4, 8, 12, and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

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

Intervention group: Patients receive 30mg of intravenous Ketorolac in 50cc normal saline before surgical incision

Category

Prevention

2**Description**

Intervention group: Patients receive 2gr of Apotel in 50 cc of normal saline before surgical incision

Category

Prevention

3**Description**

Control group: Patients receive 50cc of normal saline before surgical incision

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Seyed Mohammad Reza Safavi Homami

Street address

Al-Zahra Hospital, Sefa Boulevard, Shahid Keshvari Highway, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

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

Seyed Mohammad Reza Safavi Homami

Position

Anesthesiologist

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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

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