

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the effect of Apotel and Ketorolac before surgery on pain and the need for narcotics after abdominal surgery during the first 24 hours after surgery.

Protocol summary

Study aim

Determining the effect of Apotel and Ketorolac before surgery on pain and the amount of narcotic consumption after abdominal surgery during the first 24 hours after surgery.

Design

A double-blind randomized clinical trial study, phase 3, with two groups (a group of Apotel 1 gram intravenously and a group of Ketorolac 30 mg intravenously) with a sample size of 64 people in each group. Patients are divided into two groups by online random number table.

Settings and conduct

The location of this clinical trial study is in Bo Ali Hospital, Tehran. The drugs were divided A/B by the head of the surgery department (a group of Apotel 1 g intravenously and a group of Ketorolac 30 mg as a honey injection). Due to the double-blindness of the study, the doctor and the patient will not know which group the patient is in. Medicines were administered to the patients upon entering the operating room and in the recovery room.

Participants/Inclusion and exclusion criteria

Electiveness of action ASA1,2 (American Society of Anesthesiologists) Age 18-65 years Signing a personal consent form to enter the study Non-use of drugs, alcohol, cigarettes and psychotropic drugs Exclusion criteria: Loss of consciousness Hemodynamic disorder Abnormal intraoperative bleeding The length of the operation is more than 4 hours

Intervention groups

One hour before the operation, one group received 1 gram of Apotel intravenously and one group received 30 mg of Ketorolac as a honey injection

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230911059408N1**

Registration date: **2023-10-13, 1402/07/21**

Registration timing: **prospective**

Last update: **2023-10-13, 1402/07/21**

Update count: **0**

Registration date

2023-10-13, 1402/07/21

Registrant information

Name

Samira Sohrabpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2240 1015

Email address

samirasohrabpour@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-22, 1402/07/30

Expected recruitment end date

2024-03-20, 1403/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Apotel and Ketorolac before surgery on pain and the need for narcotics after abdominal surgery during the first 24 hours after surgery.

Public title

Comparación de los efectos de Apotel y Ketorolac antes de la cirugía sobre el dolor y la cantidad de narcóticos necesarios después de la cirugía abdominal

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Elective surgery ASA1,2 (American Society of Anesthesiologists) Age 18-65 years Signing a personal consent form to enter the study No abuse of drugs, alcohol, cigarettes and psychotropic drugs

Exclusion criteria:

Loss of consciousness Hemodynamic disorder Abnormal intraoperative bleeding The length of the operation more than 4 hours

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients were randomly divided into two groups A and B. The randomization method was performed as follows: First, a list of random numbers was generated using Excel software (using the Random Number Generation option). Then, these numbers were randomly assigned to patients. To maintain randomness, random numbers were generated and distributed by an individual independent of the study. In this study, block randomization method was used. In this method, patients were divided into small blocks and then each block was randomly assigned to one of two groups. The following method was used to randomize 128 patients into two groups of 64: First, the patients were divided into 16 blocks of 8 people (each block includes 4 people from group A and 4 people from group B, and each block will have 8 words from A and B). After that, in each block, people enter the groups randomly. Randomization will be done inside each block based on the table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

This research is a double-blind clinical trial (in order to make this study double-blind, the drugs used for the patients at the beginning of the study are A/B by the

supervisor of the surgery department so that the clinical caregiver and the participants do not know the type of drug received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address

Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabbarja St., Doktor Shariati St., Doktor Shariati St., Tehran

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2023-09-04, 1402/06/13

Ethics committee reference number

IR.IAU.PS.REC.1402.362

Health conditions studied

1

Description of health condition studied

Pain after abdominal surgery

ICD-10 code

T81.9

ICD-10 code description

Unspecified complication of procedure

Primary outcomes

1

Description

Pain

Timepoint

1, 6, 12, 24 hours after the operation

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One hour before the operation, one group receives 1 gram of Apotel intravenously.

Category

Prevention

2

Description

Control group: One hour before the operation, one group receives a 30 mg ketorolac ampoule as a honey injection.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bo Ali Hospital

Full name of responsible person

Mahnaz Narimani Zamanabadi

Street address

Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Majid Naqipour

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mahnaz Narimani Zamanabadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

SAMIRA SOHRABPOUR

Position

student

Latest degree

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Other areas of specialty/work

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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 further information

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