Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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 Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran
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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
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Sponsors / Funding sources

1

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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
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
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Associate professor
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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