Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the impact of infusion Apotel and Ketorolac in reducing postoperative pain and opioid consumption in patients undergoing orthopedic surgery of lower limbs.

Protocol summary

Summary

The aim of this projection is comparative study of the impact of infusion Apotel and Ketorolac in reducing postoperative pain and opioid consumption in patients undergoing orthopedic surgery of lower limbs. It is a randomized double blind clinical trial.Patients and the person administering the drug do not know the type of medication. After obtaining written informed consent from all patients, 60 patients candidate for orthopedic surgery of lower limbs between 20 to 60 year with American society of Anesthesiologists(ASA) physical starus 1 or 2 entered this study. Patients with history of cardiovascular; pulmonary; renal failure; treatment with warfarin and pregnant women excluded from this study.From Balanced block method ;The patients were randomly devided into two groups, Apotel and Ketorolac groups. The first group used 1 g Apotel per 6 hours and the second used 90 mg Ketorolac stat. For analysing, we used from VAS system in 0; 12 and 24 hours after surgery. The end, Pain; Nousea and Vomiting; opioid consumption analysed.

General information

Acronym

Ketorolac and Apotel and reducing of pain

IRCT registration information

IRCT registration number: **IRCT2017091231642N2**
Registration date: **2017-11-18, 1396/08/27**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-11-18, 1396/08/27

Registrant information

Name

Mohadese Esmailnejad

Name of organization / entity

Ardebil University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Ardabil University of Medical Sciences

Expected recruitment start date

2017-09-12, 1396/06/21

Expected recruitment end date

2017-09-27, 1396/07/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the impact of infusion Apotel and Ketorolac in reducing postoperative pain and opioid consumption in patients undergoing orthopedic surgery of lower limbs.

Public title

Comparative study of the impact of infusion Apotel and Ketorolac in reducing postoperative pain and opioid consumption in patients undergoing orthopedic surgery of the lower limbs.

Purpose

Treatment

Inclusion/Exclusion criteria

Entry criteria: age 20-60 ; Score pain less than 8 Exit criteria: history of cardiovascular disease ; renal disease ; treatment with warfarin ; pregnant women

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethical Committee of Ardabil University of Medical Sciences

Street address

Ardebi University of Sciencesl, Daneshgahe st, Ardebil.

City

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Postal code

53141_56198

Approval date

2017-06-14, 1396/03/24

Ethics committee reference number

IR.ARUMS.REC.1396.46

Health conditions studied

1

Description of health condition studied

Postoperative pain of orthopedic surgery

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain.

Primary outcomes

1

Description

Receive pain medication

Timepoint

24 hours study

Method of measurement

Receiving an analgesic

2

Description

pain

Timepoint

12 and 24 hours after surgery

Method of measurement

Visual Analoge Scale(VAS) system

Secondary outcomes

empty

Intervention groups

1

Description

After orthopedic surgery of lower limbs, In first group, we use ; Ampul Apotel 1 gr IV per 6 hours.

Category

Treatment - Drugs

2

Description

In secound group of this study Ampul Ketorolac 90 mg in 1 lit Serum N/S infused.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemi hospital in Ardebil

Full name of responsible person

Mina Mirzaei

Street address

Street Imam Khomeini, Shariati Sq, Fatemi Hospital

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ardabil University of Medical Sciences

Full name of responsible person

Dr.Maoud Entezari Asl

Street address

Ardebil University of Medical Sciences, Daneshgah st, Ardebil.

City

Ardebil

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 of Ardabil 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

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Position

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Other areas of specialty/work

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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