

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of the effect of ketorolac, paracetamol and saline on the pain and the need for morphine in patients undergoing surgery via video thoracoscopy

Protocol summary

Summary

The purpose of this study is comparison of the effects of Ketorolac, paracetamol and saline on the pain and the need for morphine in patients undergoing surgery via video thoracoscopy. This study is a randomized double-blind, placebo-controlled, and will be done on 93 patients candidates for video thoracoscopy surgery and are classified as class 1 to 3 of the Anesthesia Association of America, and do not have any history of heart failure or kidney failure or uncontrolled systemic disease. The patients receive the same anesthetic and sedation and , the patient transfer to the recovery room after the surgery and at that time the patients immediately undergo intravenous injection with paracetamol (apotel), Ketorolac and normal saline. The patients in the first 24 hours after surgery are under drug infusion. GroupA receives ketorolac, and group B receives Apotel and group C receives only saline in 24 hours. Patient pain intensity will be assessed with using a visual analogue scale rating of zero (no pain) to 10 (worst pain imaginable). Mean arterial pressure, heart rate and arterial oxygen saturation will be recorded at this time too. At the end the amount of morphine of the three groups will be compared. Complications such as bleeding in the first 24 hours after surgery, respiratory distress will recorded also.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062412642N14**

Registration date: **2015-07-11, 1394/04/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-07-11, 1394/04/20

Registrant information

Name

Majid Golestani Eraghi

Name of organization / entity

Shahid Beheshti University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Deputy for Research and Technology Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of ketorolac, paracetamol and saline on the pain and the need for morphine in patients undergoing surgery via video thoracoscopy

Public title

effect of ketorolac and paracetamol on pain in patients undergoing surgery via video thoracoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: All patients undergoing surgery via video thoracoscopy; Lack of heart failure; Lack of renal failure; Lack of uncontrolled systemic disease; lack of mental retardation; Lack of addiction to drugs and alcohol; lack of sychiatric disease and depression
exclusion criteria: Lack of consent to participate in the study; Sensitivity to study drugs

Age

From **18 years** old to **99 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Deputy for Research and Technology Shahid Beheshti University of Medical Sciences

Street address

Daneshjoo Ave, Velenjak

City

Tehran

Postal code

Approval date

2015-06-09, 1394/03/19

Ethics committee reference number

FBMU1.REC.1394.113

Health conditions studied

1

Description of health condition studied

Effect of intravenous analgesics in patients undergoing

surgery via video thoracoscopy

ICD-10 code

F44.6

ICD-10 code description

Dissociative anaesthesia and sensory loss

Primary outcomes

1

Description

Heart rate

Timepoint

Immediately after recovery and 2, 4, 8, 12 and 24 hours after surgery

Method of measurement

in minute

2

Description

mean arterial pressure

Timepoint

Immediately after recovery and 2, 4, 8, 12 and 24 hours after surgery

Method of measurement

mmHg with Using a mercury manometer

3

Description

pain

Timepoint

Immediately after recovery and 2, 4, 8, 12 and 24 hours after surgery

Method of measurement

Using a visual analogue scale of pain

Secondary outcomes

1

Description

amount use of morphine

Timepoint

24 passed after surgery

Method of measurement

According mg

2

Description

Saturation of arterial blood

Timepoint

Immediately after recovery and 2, 4, 8, 12 and 24 hours after surgery

Method of measurement

with pulse oxymetry

Intervention groups

1

Description

Group C: saline is administered after the end of surgery, then saline continues for 24 hours

Category

Prevention

2

Description

Group A: ketorolac 30mg is administered after the end of surgical, then ketorolac continues 90mg for 24 hours

Category

Prevention

3

Description

Group B: Apotel 1gr is administered after the end of surgical, then apotel continues 3gr for 24 hours

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Majid Golestani Eraghi

Street address

Darabad Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy for Research and Technology Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Daneshjoo Ave, Velenjak

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy for Research and Technology Shahid Beheshti 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Department of Anesthesia Shahid Beheshti University Of Medical Science

Full name of responsible person

Alireza Jahangirifard

Position

Fellowship of Cardiac Anesthesia

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Anesthesia group, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Majid Golestani Eraghi

Position

Fellowship specialty intensive care

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