

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing Of Ketrolac Plus Apotel and Meperidine in Decrease Of Pain After Right Thoracotomy

Protocol summary

Study aim

The aim of this study was to evaluate and compare the effect of the meperidine versus apotel-ketorolac combination in reducing post-thoracotomy pain in patients.

Design

A clinical trial with parallel, double-blind, randomized, phase 2 groups on 60 patients. Used for randomization using SPSS software.

Settings and conduct

This study is randomization. The statistical population includes 60 patients who are candidates for right thoracotomy surgery who are referred to Ghaem Hospital. In this study, 60 ASA class 2 patients in the age group of 18 to 70 years were selected as candidates for right thoracotomy surgery and were satisfied with the study.

Participants/Inclusion and exclusion criteria

The study is random. The statistical population includes 60 patients who are candidates for right thoracotomy surgery who are referred to Ghaem Hospital. In this study, 60 ASA class 2 patients in the age group of 18 to 70 years were selected as candidates for right thoracotomy surgery and were satisfied with the study.

Intervention groups

At the beginning of a recovery in the intervention group, one gram of paracetamol and 30 mg of ketorolac as an infusion are prescribed to reduce and control pain. Before the operation, the patient is instructed to express the amount of pain based on the measurement system 1 as the minimum (tolerable) and 10 (unbearable) and during the patient's stay in recovery (average 2 hours) the patient monitors the amount of pain. It is the basis of NRS criteria and vital signs. And repeat control of the control group will be done in case of restlessness of the disease.

Main outcome variables

Blood pressure - transpiration - oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210921052538N1**

Registration date: **2022-06-08, 1401/03/18**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-08, 1401/03/18**

Update count: **0**

Registration date

2022-06-08, 1401/03/18

Registrant information

Name

Mohammad Salehi Ali Abad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3604 9687

Email address

salehiam1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-26, 1400/10/05

Expected recruitment end date

2022-06-26, 1401/04/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing Of Ketrolac Plus Apotel and Meperidine in Decrease Of Pain After Right Thoracotomy

Public title

Comparing Of Ketrolac Plus Apotel and Meperidine in Decrease Of Pain After surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing right thoractomy

Exclusion criteria:

epidural / spinal anesthesia Patients with a history of addiction Patients with a history of coagulation disorders and platelets less than one hundred thousand. until the History of kidney failure Serum creatinine more than one and a half Patients with a history of hyperthyroidism

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization will be used as a reliable randomization method. For this purpose, an online website addressed as (<https://www.sealedenvelope.com/simple-randomiser/v1/lists>) is used to create random blocks with different sizes depending on the total sample and proposed block sizes (4 and 6). Each block content is sealed. One of the block is randomly chosen when a patient refers. The patient is assigned to one of the study arms depending on the block content. Similarly, after the completion of the first block, the second block is randomly selected and this continues until the last block and the last patient is assigned to the study arms. By assigning the last sheet of the last block, the patients are grouped equally in the two study arms.

Blinding (investigator's opinion)

Double blinded

Blinding description

The method of the envelope is that the envelopes will be prepared and printed by one of the members of the research team and random numbers with the help of Randomaize.com site and will be placed inside the envelope. The lid of the envelope will be closed and its contents will not be visible from the outside. Then, the purpose of the study is first explained to the person who meets the conditions, and the person, if desired, signs the informed consent form and takes an envelope, and then opens it and enters the intervention or control group based on the contents of the envelope.

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه پزشکی مشهد

Street address

No. A7- 4th amin - amin street- Sajad BLVD

City

مشهد

Province

Razavi Khorasan

Postal code

9187953868

Approval date

2021-09-20, 1400/06/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1400.397

Health conditions studied

1

Description of health condition studied

surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood pressure,

Timepoint

Immediately after the surgery and in the recovery room at 30 minute intervals

Method of measurement

Mercury sphygmomanometer

2

Description

oxygen saturation

Timepoint

Immediately after the surgery and in the recovery room at 30 minute intervals

Method of measurement

Pulse oximeter

3

Description

transpiration

Timepoint

Immediately after the surgery and in the recovery room
at 30 minute intervals

Method of measurement

Ocular observation

4

Description

pain level

Timepoint

Immediately after the surgery and in the recovery room
at 30 minute intervals

Method of measurement

Pain questionnaire

Secondary outcomes

1

Description

pulse

Timepoint

30 min

Method of measurement

heart monitoring

Intervention groups

1

Description

Control group: receive meperidine in case of pain (0.5
-1mg/kg)

Category

Treatment - Drugs

2

Description

Intervention group: Intravenous ketorolac -
paracetamol: At the beginning of recovery in the
intervention group, one gram of paracetamol and 30 mg
of ketorolac as an infusion are prescribed to reduce and
control pain. (the ketorolac is bought from exire co (Iran).
And the paracetamol was bought from Unifarma co (Iran)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Ghaem hospital

Full name of responsible person

Allireza Sharifian

Street address

Ahmadabad street

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Mashhad

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Razavi Khorasan

Postal code

9118953868

Phone

+98 51 3604 9687

Email

Salehiam1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Majid Ghayour-Mobarhan

Street address

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City

Mashhad

Province

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Email

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Grant name

Dr. Majid Ghayour Mobarhan

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Alireza Shariifian

Position

associated professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Alireza sharifiian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

mohammad Salehi

Position

residence

Latest degree

Medical doctor

Other areas of specialty/work

Biochemistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

professor and student of university

Under which criteria data/document could be used

Mashhad medical student

From where data/document is obtainable

No 7- 4th Amin- Amin street - Sajad BLVD-

What processes are involved for a request to access data/document

email request

Comments