Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Oct 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
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Iran (Islamic Republic of)
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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 ketrolac 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 Sharifiian
Street address
Ahmadabad street
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۹۱۸۷۹۵۳۸۶۸
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Majid Ghayour-Mobarhan
Street address
Daneshagah Street -ghoresi buliding
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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
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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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Email
Salehiam1@mums.ac.ir

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