Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Analgesic effects of intrapleural pethedine after operations with chest tube insertion

Protocol summary

Study aim
Determining the effectiveness of intrapleural pethidine on postoperative pain in patients undergoing chest tubing

Design
A clinical trial study with an intervention group (receiving pethidine intrapleural) and a control group (without drug) which is a randomized controlled study without blinding in 2 groups of 29 people using random blocks.

Settings and conduct
The study was performed on 58 patients in need of surgery with chest tube in Qazvin city hospital in 1400. Patients are divided into two groups receiving pethidine or the control group. The amount of pain based on VAS in the first hours, 6, 12, 18 and 24 hours after surgery in both groups is determined and compared. In this study, blindness was not performed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Perform surgery with chest tube insertion Exclusion criteria: pethidine allergy, drug addiction

Intervention groups
Intrapleural pethidine intake ؛ not receiving pethidine

Main outcome variables
The effectiveness of intraploral pethidine on pain intensity and infection rate in hospitalized patients

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210825052291N1**
Registration date: **2021-11-23, 1400/09/02**
Registration timing: **prospective**

Last update: **2021-11-23, 1400/09/02**
Update count: **0**

Registration date
2021-11-23, 1400/09/02

Registrant information
Name
Mohammad Darvishvand
Name of organization / entity
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Iran (Islamic Republic of)
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+98 28 3379 0627
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Analgesic effects of intrapleural pethedine after operations with chest tube insertion

Public title
Analgesic effects of intrapleural pethedine after operations with chest tube insertion

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Perform the operation with a chest tube
Exclusion criteria:

Allergy to pethidine Drug addiction

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups a and b using the balance block randomization method. The size of each block is 4.Balanced randomization method for participants in the clinical trial study is a randomized control, the effect of intrapleural injection of pethidine (group a) and no injection (group b) in reducing pain after chest tubing. Random allocation tool is software.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Velayat hospital,22 Bahman boulevard,Elahieh alley, Minoodar town,Qazvin

City

Qazvin

Province

Qazvin

Postal code

3471976161

Approval date

2020-12-30, 1399/10/10

Ethics committee reference number

IR.QUMS.REC.1399.371

Health conditions studied

1

Description of health condition studied

Chest tube placement

ICD-10 code

R07.8

ICD-10 code description

Other chest pain

Primary outcomes

1

Description

Intensity of pain

Timepoint

The first hours, 6, 12, 18 and 24 hours after surgery

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

infection

Timepoint

The first hours, 6, 12, 18 and 24 hours after surgery

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: Intraploral pethidine injection (injection of pethidine locally into the intraploral space between the parietal and visceral pleura through a catheter causes regional analgesia of the chest).Each injection of 25 mg for 2 minutes from a pethidine vial is given to the patient locally. The patient's vital signs are constantly monitored during the injection.

Category

Treatment - Drugs

2

Description

Control group: Control group, no injection of pethidine (in this group, pethidine is not used, only local anesthetics are used, which are prescribed in the same amount in the intervention group).

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Vellayat Hospital

Full name of responsible person

Mohammad Darvishvand
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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ali32024@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Mohammad Darvishvand
Position
Resident
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
All data can be shared after individuals are unidentified.
When the data will become available and for how long
Access starts 6 months after the results are published
To whom data/document is available
The data will be available to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
Any kind of analysis on the delivered data is allowed. Send a message to the author's email to request access to data or documentation.
From where data/document is obtainable
Refer to the email of Dr. Mohammad Darvishvand
What processes are involved for a request to access data/document
After the publication of the article, the applicant is able to access the information by sending an email to the author and its duration is about one month.
Comments