

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Analgesic effects of intrapleural pethidine 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 intrapleural 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3379 0627

###### Email address

nafis.rastgoo.20@gmail.com

##### 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 pethidine after operations with chest tube insertion

##### Public title

Analgesic effects of intrapleural pethidine 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: Intrapleural pethidine injection (injection of pethidine locally into the intrapleural 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

Velayat Hospital

##### Full name of responsible person

Mohammad Darvishvand

**Street address**

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

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ali32024@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr Sepideh Hajian

**Street address**

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

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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

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

**Street address**

Vellayat Hospital,Qazvin

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## Person responsible for scientific inquiries

#### Contact

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**Full name of responsible person**

Mohammad Darvishvand

**Position**

Resident

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## Person responsible for updating data

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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**