

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effect of intrapleural morphine and pethidine injection to control postoperative pain in trachotomy surgeries

Protocol summary

Study aim

Determining and comparing the effect of intrapleural injection of morphine and pethidine on postoperative pain control in tracheotomy surgeries.

Design

A clinical trial with a control group, with parallel groups, double-blind, on 72 patients, Randomized by the method of Balanced Block Randomization

Settings and conduct

A double-blind clinical karma study is conducted in Qazvin Hospital on patients who are candidates for thoracotomy surgery. The patient, the researcher, and the treating doctor do not know about the content of the injected substance. The patients are divided into three groups of 24 people. In all three groups, before extubation, a catheter is inserted to inject drugs: 1. Morphine injection 2. Pethidine injection 3. Normal saline injection. After entering the ward, the level of pain is checked. Diclofenac 100 suppositories 100 suppositories for moderate pain and severe pain vas>7 morphine 5 mg are prescribed intravenously.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 25-65; Candidate for thoracotomy surgery; ASA class I or II; Informed consent
Non-inclusion criteria: Alcohol and drug addiction; Drug sensitivity and allergy; Previous chronic pains; Epilepsy

Intervention groups

72 patients were selected and randomly divided into 3 groups of 24 as follows: Group A: Morphine injection of 0.1 mg/kg in 40 ml of saline in the intrapleural space. Group B: injection of Pethidine 1 mg/kg in 40 ml of saline in the intrapleural space Group C: injection of 40 ml of Normal Saline in the intrapleural space

Main outcome variables

The intensity of pain;The duration of hospitalization; The amount of narcotic drug injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230828059289N1**

Registration date: **2023-11-04, 1402/08/13**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-04, 1402/08/13**

Update count: **0**

Registration date

2023-11-04, 1402/08/13

Registrant information

Name

safieh salim pour abkenar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3379 0620

Email address

salimpour67@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2024-09-10, 1403/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of intrapleural morphine and pethidine injection to control postoperative pain in tracheotomy surgeries

Public title
Comparison of the effect of morphine and pethidine injections into the pleural space to control postoperative pain in tracheotomy surgeries

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age range 25-65 Candidate for tracheotomy surgery ASA class I or II Existence of informed consent
Exclusion criteria:
Alcohol and drug addiction Drug sensitivity and allergy Previous chronic pain Epilepsy

Age
From **25 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are assigned to three treatment groups A, B, and C using the method of random blocks (Balance block randomization), the size of each block is 6 and the total number of blocks is 12. The balanced randomization allocation method for the participants in the randomized controlled clinical trial study is in the first group (A), the second group (B) and the third group (C); The variables are measured and compared between the three groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
The surgical resident receives the drugs which are coded in closed envelopes and injects them into the patients. Coding is done by one of the colleagues of the project and the doctor, surgical resident, and patient are blinded.

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

Research and Technology deputy, 1st Branch, Maudet Alley, Shahid Beheshti Blvd, Qazvin

City

Qazvin

Province

Qazvin

Postal code

3415613911

Approval date

2023-08-12, 1402/05/21

Ethics committee reference number

IR.QUMS.REC.1402.110

Health conditions studied

1

Description of health condition studied

Pain control after thoracotomy

ICD-10 code

G89.12

ICD-10 code description

Acute post-thoracotomy pain

Primary outcomes

1

Description

Severity of pain after surgery

Timepoint

From the time of admission to the ward until the time of discharge

Method of measurement

Visual Analog Scale

2

Description

Duration of hospitalization

Timepoint

From the time of admission to the ward until the time of discharge

Method of measurement

Check list

3

Description

The amount of narcotic drug injection

Timepoint

From the start of the surgery to the time of discharge

Method of measurement

Check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A: Morphine injection (Darou pakhsh Iran company) with a dose of 0.1 mg/kg in 40 ml of saline in the intrapleural space

Category

Treatment - Drugs

2

Description

Intervention group: Group B: Pethidine injection (Pharmaceutical Co. Caspian Tamin) with a dose of 1 mg/kg in 40 ml of saline in the intrapleural space.

Category

Treatment - Drugs

3

Description

Control group: Group C: injection of 40 ml of normal saline in the intrapleural space

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Safieh Salimpour Abkenar

Street address

22bahman Blvd, Tavon Square, Elahiye Quay,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Seyed Mahidi Mirhashemi

Street address

Mavaddat Alley ,Research and Technology deputy,
Shahid Beheshti Blvd, Qazvin

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Email

researchdpt@qums.ac.ir

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

Safieh Salim pour abkenar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

Street address

22 Bahman Blvd, Tavon Square, Elahiye Quay,
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salimpour67@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

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Position

Resident

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Safieh Salim pour abkenar

Position

Resident

Latest degree

Medical doctor