Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 trachotomy 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, Minodar Town
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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
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22 Bahman Blvd, Tavon Square, Elahiye Quay, Minodar Town
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Person responsible for scientific inquiries

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Name of organization / entity
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Full name of responsible person
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Position
Resident

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Person responsible for updating data

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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