

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of local administration of bupivacaine and dexamethasone combination with bupivacaine administration only in postoperative pain in patients undergoing thoracotomy

Protocol summary

Study aim

Determination of the effect of local administration of bupivacaine and dexamethasone with bupivacaine administration only in postoperative pain in patients undergoing thoracotomy

Design

Clinical trial with control group, double blind, randomized, phase 2-3 on 40 patients. Randomization is done by Randomizer software.

Settings and conduct

This double blind study was done in Amin & Alzahra hospitals (Isfahan, IRAN). Only surgical technologist know which drug is administered. After closing the chest wall in the intervention group, the 2.5 mg of bupivacaine per kilogram of weight is injected with 0.2 mg per weight of dexamethasone in the catheter. In the control group, the 2.5 mg of bupivacaine per kilogram of weight is injected in the catheter. After 6 hours, this amount of drug in the control and intervention groups is injected in the catheter.

Participants/Inclusion and exclusion criteria

Patients who are candidate for thoracotomy include in the study. In case of allergy to the drugs used, patients will not enter the study.

Intervention groups

Intervention group 1: Local Bupivacaine and dexamethasone. Intervention group 2: Local Bupivacaine only.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220309054226N1**

Registration date: **2022-03-21, 1401/01/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-21, 1401/01/01**

Update count: **0**

Registration date

2022-03-21, 1401/01/01

Registrant information

Name

Pouriya Sarboloukzadeh harandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

dr.pooriasharandi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of local administration of bupivacaine and dexamethasone combination with bupivacaine administration only in postoperative pain in patients undergoing thoracotomy

Public title

Comparison of the effect of local administration of bupivacaine and dexamethasone combination with bupivacaine administration only in postoperative pain in patients undergoing thoracotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidate for thoracotomy Consent to participate in the study

Exclusion criteria:

History of allergy to the used medications

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization to two groups of 20 people using Randomizer software. This is done by introducing the file number to the software and random allocation order into two groups of 20. This randomization was done by a trained person, but without interference in the research process, and output information is only observed by operating room technicians at the time of operation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Only surgical technicians are aware of the drug(s) that used and the doctor 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 Isfahan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Hezar Jerib St.sfahan University of MedicalSciences and

Health Services, Building No. 4

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2022-02-20, 1400/12/01

Ethics committee reference number

IR.MUI.MED.REC.1400.811

Health conditions studied

1

Description of health condition studied

Acute post-thoracotomy pain

ICD-10 code

G89.12

ICD-10 code description

Acute post-thoracotomy pain

Primary outcomes

1

Description

Acute post-thoracotomy pain

Timepoint

6, 12 and 24 hours after surgery

Method of measurement

Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Local injection of 2.5 milligram bupivacaine (AuroMedics Pharma LLC, USA) and 0.2 milligram dexamethasone (Caspian Tamin, IRAN) per kilogram of body weight in the subpleural catheter

Category

Treatment - Drugs

2

Description

Control group: Local injection of 2.5 milligram bupivacaine (AuroMedics Pharma LLC, USA)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Pouriya Sarboloukzadeh Harandi

Street address

Alzahra Hospital, Sofeh Blvd.

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Isfahan

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Phone

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Email

alzahra@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash

Street address

Vice Chancellor for Research and Technology, Hezar
Jerib St.sfahan University of Medical Sciences and
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research@mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Pouriya Sarboloukzadeh Harandi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Information is kept confidential
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
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
Not applicable
Title and more details about the data/document
Information about the main outcome can be shared
When the data will become available and for how long
After publishing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Using data to complete studies
From where data/document is obtainable
Dr. Pouriya Sarboloukzadeh Harandi, Isfahan University of Medical Sciences
What processes are involved for a request to access data/document
By examining the researcher's request and providing sufficient documentation of his research and the reason for using the data can be provided
Comments