

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Assessment of local bupivacain injection effect in comparison of placebo for relieving of acute post - thoracotomy pain in patients who undergoing thoracotomy.

Protocol summary

Summary

Objectives: The aim of this study is to evaluate the effect of local bupivacaine which inject at the incision line before surgery in the management of pain after thoracotomy surgery. **Study Design:** In a randomized, double-blind clinical trial all patients who candidate for thoracotomy divide into two groups (case and control). **Setting and conduct:** Patients enroll in the study after written informed consent, complete history take and all subjects undergo physical examination and preoperative evaluation. All patients receive general anesthesia and surgical procedures are the same for all, intercostals blocks perform at the end of the operation for all patients. A person who inject and nurses do not know about patients' group, so patients receive analgesics as routine and its amount will be recorded. **Participants, inclusion and exclusion criteria:** All patients who candidate for elective thoracotomy enroll. **Inclusion criteria:** Patients age between 10 to 70 years old. **Exclusion criteria:** drug addictions and chest pain in previous history. **Interventions:** In the first group after anesthesia and before thoracotomy incision, 2mg/kg bupivacaine 0.5% diluted by distilled water inject subcutaneously around the site of the incision line, so that infiltrate the entire length of the incision. In control group a placebo (normal saline 0.9%) will inject as same volume and same way which is performing for patients group. **The main outcome variables:** The main outcome variables are severity of pain and need to analgesics.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052313437N1**
Registration date: **2014-01-06, 1392/10/16**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-01-06, 1392/10/16

Registrant information

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Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Semnan University of Medical Sciences

Expected recruitment start date

2013-10-23, 1392/08/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of local bupivacain injection effect in comparison of placebo for relieving of acute post - thoracotomy pain in patients who undergoing thoracotomy.

Public title

Effect of local bupivacain injection on acute post-thoracotomy pain.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 10 -70 years old
Exclusion criteria: Drugs abuse; Chest pain in previous history.

Age

From **10 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Semnan University of Medical Sciences

Street address

Basidj Boulevard

City

Semnan

Postal code

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

91/16/16595

Health conditions studied

1

Description of health condition studied

pain after thoracotomy

ICD-10 code

G89.12

ICD-10 code description

Acute pain after thoracotomy

Primary outcomes

1

Description

pain severity in thoracotomy incision site

Timepoint

2, 4, 8, 24 hours after thoracotomy

Method of measurement

Visual analogue scale (VSA)

Secondary outcomes

1

Description

Need to analgesics

Timepoint

After termination of surgery

Method of measurement

monitoring

Intervention groups

1

Description

The first group after anesthesia and before thoracotomy incision, 2mg/kg bupivacaine 0.5% diluted by distilled water inject subcutaneously around the site of the incision line, so that the entire length of the incision infiltrate.

Category

Treatment - Drugs

2

Description

In control group after anesthesia and before thoracotomy incision a placebo (normal saline 0.9%) will inject subcutaneously around the site of the incision line, so that the entire length of the incision infiltrate.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Momenin Hospital

Full name of responsible person

Farzaneh Hussein

Street address

Imam Hussein square

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Semnan University of Medical Sciences

Full name of responsible person

Raheb Ghorbani

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Semnan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty