

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of naproxen on post-operative pain of thoracotomy, a randomized, blinded diclofenac control study

Protocol summary

Study aim

Effect of naproxen on post-operative pain of thoracotomy

Design

Randomized double blinded controlled study with 60 patients needing thoracotomy surgery that referred to Masih Daneshvari Hospital will be chosen and a code will be allocated to each one of them. Then, patients will randomly divided into three control and intervention groups.

Settings and conduct

This study was a blind, randomized, double blinded study that in the thoracotomy surgery department of Masih Daneshvari Hospital affiliated to Shahid Beheshti University of Medical Sciences, Tehran, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who are between 25 and 65 years of age and in proper physical condition for thoracotomy surgery. Exclusion criteria: Patients with a history of gastric ulcer disease, bleeding disorders, kidney failure and patients that used nonsteroidal anti-inflammatory drugs.

Intervention groups

Intervention group1: Naproxen suppository 500 mg, 30-60 minutes before thoracotomy Intervention group 2: Diclofenac suppository 100 mg, 30-60 minutes before thoracotomy surgery Control group: not receiving any pain medication before surgery.

Main outcome variables

pain, Postoperative pain score is measured for all patients using the VAS technique in 0, 30, 60, 90 minutes, 2, 4, 6, 10, 24 hours after surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160813029327N16**

Registration date: **2018-07-28, 1397/05/06**

Registration timing: **retrospective**

Last update: **2018-07-28, 1397/05/06**

Update count: **0**

Registration date

2018-07-28, 1397/05/06

Registrant information

Name

Ramin Abrishami

Name of organization / entity

Islamic Azad University, Pharmaceutical sciences branch

Country

Iran (Islamic Republic of)

Phone

+98 21 2264 1889

Email address

r_abrishami@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-02-18, 1395/11/30

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of naproxen on post-operative pain of thoracotomy, a randomized, blinded diclofenac control study

Public title

Effect of naproxen on the post-operative pain of thoracotomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients who are between 18 and 65 years of age and in proper physical condition for thoracotomy surgery. Tendency to participate in the study and having consent form

Exclusion criteria:
Patients with a history of gastric ulcer disease Serious complications from non-steroidal anti-inflammatory agents Bleeding disorders Kidney failure Patients that used non-steroidal anti-inflammatory drugs.

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

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Using Sequence Generator available at random.org three groups were made. Group 1 will receive Naproxen, Group 2 will receive Diclofenac, and Group 3 will be control group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Drugs are packed in to similar packages with ID codes; Physician, nurse, and investigators are not aware about package contents. Codes and labeling will be done by a third person.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University of Pharmaceutical Sciences

Street address

99, Yakhchal Ave., Gholhak, Shariati St.

City

Tehran

Province

Tehran

Postal code

19395-6466

Approval date

2017-03-13, 1395/12/23

Ethics committee reference number

IR.IAU.PS.REC.1396.77

Health conditions studied

1

Description of health condition studied

Patients undergoing thoracotomy due to various conditions, eg. hydatid cyst, metastasis, mediastinal mass.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain evaluation

Timepoint

0, 30, 60, 90 minutes, 2, 4, 6, 10, 24 hours after surgery

Method of measurement

VAS (Visual Analogue Scale) technique

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group 1 receives 500 mg naproxen suppository 30-60 minutes before surgery.

Category

Treatment - Drugs

2

Description

The intervention group 2 receives diclofenac suppository 100 mg at the time of 30-60 minutes before surgery.

Category

Treatment - Drugs

3

Description

Control group: no pain medication before surgery will be used.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Shokoufeh Bayat

Street address

Pour Ebtehaj street, DarAbaad

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 3000

Email

shekufeh.1993@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Farshad Hashemian

Street address

No 99, Yakhchal Avenue, Shariati street

City

Tehran

Province

Tehran

Postal code

19395-6466

Phone

+98 21 2264 0051

Email

fhashemian@yahoo.com

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Ramin Abrishami

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

No 99, the first of Yakhchal Ave., Gholhak, Shariati St.

City

Tehran

Province

Tehran

Postal code

19395-6466

Phone

+98 21226400515

Email

r_abrishami@iaups.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University of Pharmaceutical Sciences

Full name of responsible person

Ramin Abrishami

Position

Assistant professor

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Other areas of specialty/work

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Person responsible for updating data

Contact

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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

Yes - There is 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

Patients' demographic data, Visual Analogue Scale, Opioid consumption

When the data will become available and for how long

After publication of paper, for one year

To whom data/document is available

To academic persons

Under which criteria data/document could be used

User should cite the primary document

From where data/document is obtainable

Via email to corresponding author

What processes are involved for a request to access data/document

Sending email to corresponding author

Comments