Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of concurrent respiratory workout and mobility exercises on pain, anxiety and lung expansion ability in post-operative lung cancer surgery patients with chest tube

Protocol summary

Study aim
determining the effect of concurrent respiratory workout and mobility exercises on pain, anxiety and lung expansion ability in post-operative lung cancer surgery patients with chest tube

Design
a non randomized parallel clinical trial with control group, no blinding

Settings and conduct
motive exercises were performed with left or right arm depending on the side of the chest tube installation. Pain, anxiety, amount of lung secretions and the time of the chest tube removal were measured daily in the control group. Interventions were implemented after surgery in intervention group cases. research was performed at the thoracic surgery ward in Tehran Valiasr hospital; located in Imam Khomeini hospital complex.

Participants/Inclusion and exclusion criteria
inclusion criteria : two chest tubes installed, over 18 years old, completely aware of time, place and who he/she is, not taking Narcotic drugs at least 4 hours before the interventions, no sensory disorder (audio and visual), no substance addiction, not taking anti anxiety drugs, no history of lung diseases and no history of chest tube installation exclusion criteria: severe anxiety due to environmental factors, not being interested to participate, lack of learning ability, addiction

Intervention groups
Respiratory and motive workout were taught to patients of intervention group. These exercises were performed once a day until removal of the chest tube with the presence of the researcher. exercises include deep breathing, pursed lip breathing and motive exercises for arm and shoulder. There was no intervention in the control group and patients received routine care of the hospital including drug therapy, serum therapy and change of the dressings.

Main outcome variables
lung expansion mark on spirometry, measured pain using visual analog scale, measured anxiety using visual analog scale

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190427043397N1**
Registration date: **2019-07-26, 1398/05/04**
Registration timing: **retrospective**

Last update: **2019-07-26, 1398/05/04**
Update count: **0**

Registration date
2019-07-26, 1398/05/04

Registrant information

Name
Alireza Arman

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-20, 1396/12/01

Expected recruitment end date
2018-10-22, 1397/07/30

Actual recruitment start date

2018-02-20, 1396/12/01

Actual recruitment end date

2018-10-22, 1397/07/30

Trial completion date

2018-10-22, 1397/07/30

Scientific title

Effect of concurrent respiratory workout and mobility exercises on pain, anxiety and lung expansion ability in post-operative lung cancer surgery patients with chest tube

Public title

effect of respiratory and mobility exercise on pain, anxiety and lung expansion in post surgery patients with cancer

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

having 2 chest tubes installed over 18 years old completely aware of time, place and who he/she is not taking Narcotic drugs at least 4 hours before the interventions no sensory disorders (audio and visual) no substance addiction not taking anti anxiety drugs no history of lung diseases and no history of chest tube installation

Exclusion criteria:

severe anxiety due to environmental factors not being interested to participate lack of learning ability addiction

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **81**

Actual sample size reached: **81**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods street, Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2017-10-27, 1396/08/05

Ethics committee reference number

IR.TUMS.FNM.REC.1396.4524

Health conditions studied

1

Description of health condition studied

lung cancer

ICD-10 code

C34.90

ICD-10 code description

Malignant neoplasm of unspecified part of unspecified bronchus or lung

Primary outcomes

1

Description

Lung expansion mark on spirometry

Timepoint

Before interventing - after interventin (before removing chest tube)

Method of measurement

Spirometry

2

Description

measured pain using visual analog scale

Timepoint

Everyday until chest tube removal

Method of measurement

Visual Analogue Scale for pain

3

Description

measured anxiety using visual analog scale

Timepoint

Everyday until chest tube removal

Method of measurement

Visual Analogue Scale for anxiety

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: On the first visit with the patients (before surgery and installation of chest tubes) explanations about interventions and the research was given to them, then the informed consent was signed by the patient and demographic information form was filled out by the researcher. The spirometry results was observed and recorded from patient's file. Before the operation, when patient was present in the ward, and after filling forms mentioned above, instructions for respiratory workout and mobility exercises including diaphragmatic respiration, pursed lip breathing, chest physiotherapy, physical movements for arm and shoulder of the side that chest tube has been installed (whether its left or right) and using incentive spirometer were given to the patient. These instructions were conducted and controlled by the researcher. After the surgery was finished and patient was transferred to the ward, pain and anxiety were measured using visual analog scale (VAS). A checklist was given to the participant which contained all workouts that he/she was meant to do and asked to fill the checklist each time doing the exercises in order to ensure that they perform exercises correctly. The researcher controlled the checklist in order to make sure that no exercise has been missed. Participants were supposed to do the exercises ten times in one hour according to ability and clinical conditions. Therefore, participants performed each exercise that could do until it reaches ten times in one hour and doesn't make him/her tired. These activities were performed once each day on certain hours (10 AM to 12 MD) with presence of the researcher until chest tube was removed and VAS marks for pain and anxiety were written down.

Category

Prevention

2

Description

Control group: On the first visit with the patients (before surgery and installation of chest tubes) explanations about interventions and the research was given to them, then the informed consent was signed by the patient and demographic information form was filled out by the researcher. The spirometry results was observed and recorded from patient's file. There were no research related instructions given to the patients of control group. After the surgery was finished and patient was transferred to the ward, pain and anxiety were measured using visual analog scale (VAS). Pain and anxiety were measured daily on certain hours (10 AM to 12 MD) until the tubes were removed. Before the removal of the chest tubes another spirometry test was token from the patients and results were recorded.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr hospital, Imam Khomeini hospital complex

Full name of responsible person
Zahra Rooddehghan

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Dr. Qarib street, End of Keshavarz Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammad Ali Sahraian

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Tehran University of Medical Sciences, Qods st., Keshavarz blvd.

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msahrai@sina.tums.ac.ir

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http://vcr.tums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Alireza Arman

Position

MS student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

because of financial problems and costs

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable