

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of respiratory rehabilitation before and after pulmonary endarterectomy (PEA) in patients with chronic thromboembolic pulmonary hypertension (CTEPH)

Protocol summary

Study aim

The effect of respiratory rehabilitation before and after pulmonary endarterectomy (PEA) in patients with chronic thromboembolic pulmonary hypertension (CTEPH)

Design

A clinical trial with a control group, randomized with parallel groups, on 75 patients, was used for randomization using a table of random numbers.

Settings and conduct

This study is conducted as a non-blinded clinical trial on patients who are candidates for pulmonary endarterectomy surgery referred to Masih Deneshvari Hospital in Tehran, Iran. Patients enter the study after providing full explanations and signing a written consent form.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for endarterectomy surgery based on the results of echocardiography, angiography, and CPET and examinations by the treating physician at Masih Daneshvari Hospital. Exclusion criteria: if the patient does not want to exercise, relapse of the disease, or underlying disease such as diabetes and arrhythmia.

Intervention groups

The first group includes patients who perform respiratory rehabilitation exercises only after surgery. The second group includes patients who perform respiratory rehabilitation exercises before and after surgery, and the third group (control group) only receives routine treatments and does not receive any exercise intervention.

Main outcome variables

Right ventricular pressure, pulmonary artery systolic and diastolic pressure, cardiac output, pulmonary vascular resistance, pulmonary artery compliance, left ventricular extensor index, pulmonary artery systolic pressure at rest, 6-minute walking test distance, maximum VO₂,

level of fatigue during activity, dyspnea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230417057933N2**

Registration date: **2023-04-27, 1402/02/07**

Registration timing: **prospective**

Last update: **2023-04-27, 1402/02/07**

Update count: **0**

Registration date

2023-04-27, 1402/02/07

Registrant information

Name

Zargham_Hossein Ahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2002

Email address

zarghamahmadi@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of respiratory rehabilitation before and after pulmonary endarterectomy (PEA) in patients with chronic thromboembolic pulmonary hypertension (CTEPH)

Public title

The effect of respiratory rehabilitation in patients with chronic thromboembolic pulmonary hypertension (CTEPH)

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are candidates for endarterectomy based on the results of echocardiography, angiography and CPET and examinations of the attending physician at Masih Daneshvari Hospital.

Exclusion criteria:**Age**

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 75

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method, individual randomization unit and random number table randomization tool. For randomization, we use a table consisting of random digits from 0 to 9. Each of the figures in this table is repeated the same on average. In this method, each figure is assigned to a treatment group. We start from the first row of the table and move down row by row. For three groups, we put numbers 1 to 3 for the first group, numbers 4 to 6 for the second group, and numbers 7 to 9 for the third group. We continue the above process until three groups are completed.

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 Shahid Beheshti University of Medical Sciences

Street address

Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2023-04-07, 1402/01/18

Ethics committee reference number

IR.SBMU.NRITLD.REC.1402.003

Health conditions studied**1****Description of health condition studied**

Chronic thromboembolic pulmonary hypertension

ICD-10 code

I27.2

ICD-10 code description

Other secondary pulmonary hypertension

Primary outcomes**1****Description**

Right ventricular pressure

Timepoint

At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery

Method of measurement

Catheterization

2**Description**

Pulmonary artery systolic and diastolic pressure

Timepoint

At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery

Method of measurement

Catheterization

3**Description**

Mean of pulmonary artery pressure

Timepoint

At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery

Method of measurement

Catheterization

4

Description

Cardiac output

Timepoint

At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery

Method of measurement

Catheterization

5

Description

Test distance of 6 minutes walk

Timepoint

At the beginning of hospitalization, 2 weeks after rehabilitation, after surgery, 2 weeks after surgery

Method of measurement

6 minute walk test

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In this group, patients with mild symptoms do respiratory rehabilitation exercises only after surgery. They do 15 minutes of cycling with an intensity of 70% of the maximum test power and 6 minutes of walking. Patients with moderate symptoms perform 15 minutes of cycling activity with an intensity of 60% of the maximum power of the 6-minute walking test.

Category

Rehabilitation

2

Description

The second intervention group: in this group, patients perform respiratory rehabilitation exercises before and after surgery. In the pre-surgery rehabilitation program, patients with mild symptoms do 15 minutes of cycling activity with an intensity of 70% of the maximum test power of 6 minutes of walking, and patients with moderate symptoms do 15 minutes of cycling activity with an intensity of 60% of the maximum test power of 6 minutes of walking. . In the rehabilitation program after surgery: after surgery and with the opinion of a specialist doctor and surgeon, all patients will do 6 minutes of walking in each session for 20 bicycle activities with an intensity of 50 to 70% of the maximum test power. In the second week of rehabilitation, 5 minutes are added to the activity time.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Zargham Hosein Ahmadi

Street address

Masih Daneshvari Hospital, Daarabad

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2610 2020

Email

zarghamahmadi@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2243 9781

Email

zarghi@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

zarghamahmadi@hotmail.com

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohsen Abedi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Masih Daneshvari Hospital, Daarabad

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2612 5050

Email

mohsenabedi110@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zargham Hosein Ahmadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiac surgery

Street address

Masih Daneshvari Hospital, Daarabad

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2612 5050

Email

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reyhaneh Zahiri

Position

Researcher

Latest degree

Master

Other areas of specialty/work

Researcher

Street address

Masih Daneshvari Hospital, Daarabad

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2610 2020

Email

zahirireyhane@gmail.com

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