Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Shahid Abbas Arabi St., Yemen St., Shahid Chamran Highway
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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
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

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

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Person responsible for scientific inquiries

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Position
Associate professor

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Subspecialist

Other areas of specialty/work
Cardiac surgery

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Person responsible for updating data

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Position
Researcher

Latest degree
Master

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Researcher

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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