Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Effect of 8 weeks High-Intensity Interval Training on Aerobic Capacity, Pulmonary Function, Quality of Life, and Right Ventricular Function in Patients with Acute Pulmonary Embolism: A Randomized Control Trial Study, a Pilot Study

Protocol summary

Study aim

The aim of the present study is to evaluate the effect of High-intensity interval training aerobic capacity, pulmonary function, right ventricular function, and quality of life in patients with acute pulmonary embolism.

Design

The patients with acute pulmonary embolism will be selected and based on computer randomization put in 2 groups: intervention and control. Intervention group will receive exercise training and control group received only usual care.

Settings and conduct

The present study is a non-blind study and will be conducted in Tehran Heart Center, Tehran, Iran. 2 to 4 weeks after discharge, the patients will be randomized into two groups and they will perform tests. After 8 weeks, the patients will repeat the test again.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Between 18-70 Years old; admitted with acute pulmonary embolism confirmed by pulmonary CT angiography; signed informed consent. Exclusion Criteria: History of recurrent pulmonary embolism; Low-risk pulmonary embolism; Have an elective procedure that would interrupt their exercise program; Unable to participate in an exercise program; Pregnancy; Unable to read and understand the consent form

Intervention groups

Intervention group: high-intensity interval training program The control group: usual care without any rehabilitation intervention

Main outcome variables

Aerobic capacity, pulmonary function, quality of life, right ventricular function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170111031884N2**
Registration date: **2019-12-24, 1398/10/03**
Registration timing: **retrospective**

Last update: **2019-12-24, 1398/10/03**
Update count: **0**

Registration date

2019-12-24, 1398/10/03

Registrant information

Name

Amine Ghram

Name of organization / entity

Faculty of Physical Education and Sport Science, Tehran University, Tehran, Iran

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2019-09-01, 1398/06/10

Expected recruitment end date

2019-09-30, 1398/07/08

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of 8 weeks High-Intensity Interval Training on Aerobic Capacity, Pulmonary Function, Quality of Life, and Right Ventricular Function in Patients with Acute Pulmonary Embolism: A Randomized Control Trial Study, a Pilot Study

Public title
High Intensity Interval Training in Acute Pulmonary Embolism
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Between 18-70 Years old; admitted with acute pulmonary embolism confirmed by pulmonary CT angiography signed informed consent
Exclusion criteria:
History of recurrent pulmonary embolism Low-risk pulmonary embolism Unable to participate in an exercise program Pregnancy Unable to read and understand the consent form
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using Block stratified Randomization software version 6.0 via permuted block stratified randomization method with random blocks of 4, 8, 2, 6, and 10 patients. Based on this random list, individuals will be dedicated to intermittent exercise or the control group (without exercise). In order to have a random allocation sequence concealment, the list will be given to a research assistant who is unaware of the study protocol and has not a role in the study. Due to the nature of the study, blinding will not be applicable for the patients, outcome assessor and the interventionists and only the statistician is blinded to the study.
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
Research Ethics Committee of Sport Sciences Research Institute
Street address
No. 3, 5th Alley, Miremad Street, Motahhari Street, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1587958711
Approval date
2019-07-01, 1398/04/10
Ethics committee reference number
IR.SSRC.REC.1398.057

Health conditions studied

1

Description of health condition studied
Acute Pulmonary Embolism
ICD-10 code
I26
ICD-10 code description
Pulmonary embolism

Primary outcomes

1

Description
Aerobic capacity
Timepoint
before and after 8 weeks
Method of measurement
Bruce modified test

2

Description
Right ventricular function
Timepoint
before and after 8 weeks
Method of measurement
Two-dimensional and Doppler echocardiographic

3

Description
Pulmonary function
Timepoint

before and after 8 weeks

Method of measurement

Spirometry test

4

Description

Quality of life

Timepoint

before and after 8 weeks

Method of measurement

SF36 questionnaire

Secondary outcomes

1

Description

Safety

Timepoint

before, during and after intervnetion

Method of measurement

Assessed by recording the number and type of adverse events and any remedial action recorded in the patient's exercise diary and interventionist records

Intervention groups

1

Description

The intervention group will receive a 8 weeks high intensity interval training, 3 sessions per week. Each session will last 50-55 minutes.

Category

Rehabilitation

2

Description

The control group will not receive any intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran heart center

Full name of responsible person

Dr. Yaser Jenab

Street address

Tehran Heart Center, North Kargar Street, 14111713138

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research,Tehran Heart Center (TUMS)

Full name of responsible person

Dr. Saeed Sadeghian

Street address

Tehran Heart Center, North Kargar Ave, Tehran, Iran

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jenab@razi.tums.ac.ir

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,Tehran Heart Center (TUMS)

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 Heart Center

Full name of responsible person

Yaser Jenab

Position

Associate professor

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran Heart Center
Full name of responsible person
Yaser Jenab
Position
Associate Professor Of Cardiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Study protocol: The entire study protocol is shareable. Statistical Analysis Map: The entire statistical analysis map is shareable. clinical study report: The entire clinical study report is shareable. Data categorization system: The Data categorization system is shareable.
When the data will become available and for how long
Start the access period 2 months after printing results
To whom data/document is available
Researchers working in Academic Institutions
Under which criteria data/document could be used
For any kind of research in the field of medicine is possible.
From where data/document is obtainable
Amine Ghram 00989011631984
ghram.amine@hotmail.fr
What processes are involved for a request to access data/document
After sending the request by email within 2 weeks, the documentation is sent by email.
Comments