

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### **Phone**

+98 21 8802 9600

##### **Email address**

amineghram.110@ut.ac.ir

##### **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 intervention

##### **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

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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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Tehran Heart Center, North Kargar Ave, Tehran, Iran

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**Web page address**  
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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  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran Heart Center, North Kargar Ave, Tehran, Iran  
**Full name of responsible person**  
Yaser Jenab  
**Position**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**

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jenab@razi.tums.ac  
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<http://thc.tums.ac.ir>

## 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