

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Comparative study of the frequency of complications due to high-risk pulmonary thromboembolism after rapid performance of the team responsible for pulmonary embolism (TIMAR) compared to conventional performance

#### Protocol summary

##### Study aim

Comparative study of the frequency of complications due to high-risk pulmonary thromboembolism after rapid performance of the team responsible for pulmonary embolism (TIMAR) compared to conventional performance

##### Design

Clinical trial with control group with parallel groups, phase 2-3 on 74 patients

##### Settings and conduct

This study is performed in Shahid Chamran Hospital in Isfahan. Patients will be treated in two ways and the mortality rate, complications and cardiac function will be compared between groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 75 years old; diagnosis of pulmonary thromboembolism based on the GENEVA criteria; patients with high-risk pulmonary embolism; satisfaction with entering this study. Exclusion criteria: dissatisfaction with continue participation in the study.

##### Intervention groups

Intervention group: Patients in this group, whose thromboembolism has been previously proven by CT scan and Geneva criteria, are visited and evaluated by a cardiology resident and treated if patients are at high risk for thromboembolism, they will be treated according to the protocol provided by the Timar team members and the treatment plan will be implemented within a maximum of 60 minutes. Mortality and treatment complications as well as cardiac function in patients after interventions will be measured by echocardiography and checklist. Control group: patients in this group, as usual and according to hospital protocols, will be examined by a cardiology resident and their thromboembolism will be diagnosed by CT scan and Geneva criteria and will be treated by the cardiology service. Mortality and

treatment complications as well as cardiac function in patients after interventions will be measured by echocardiography and checklist.

##### Main outcome variables

The mortality rate; complications and cardiac function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210613051561N1**

Registration date: **2021-06-21, 1400/03/31**

Registration timing: **prospective**

Last update: **2021-06-21, 1400/03/31**

Update count: **0**

##### Registration date

2021-06-21, 1400/03/31

##### Registrant information

##### Name

farid esmaeili

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3778 0897

##### Email address

farid.esmaeili@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-05, 1400/05/14

**Expected recruitment end date**

2021-09-06, 1400/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of the frequency of complications due to high-risk pulmonary thromboembolism after rapid performance of the team responsible for pulmonary embolism (TIMAR) compared to conventional performance

**Public title**

Complications of pulmonary thromboembolism after rapid performance of the team responsible for pulmonary embolism

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 75 years old Diagnosis of pulmonary thromboembolism based on the GENEVA criteria Patients with high-risk pulmonary embolism Satisfaction with entering this study

**Exclusion criteria:**

Dissatisfaction to continue participation in the study

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **74**

**Randomization (investigator's opinion)**

N/A

**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 Esfahan university of Medical sciences

**Street address**

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8137866515

**Approval date**

2019-10-14, 1398/07/22

**Ethics committee reference number**

IR.MUI.MED.REC.1398.367

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

Pulmonary embolism

**ICD-10 code**

I26

**ICD-10 code description**

Pulmonary embolism

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

Mortality rate

**Timepoint**

After interventions

**Method of measurement**

Check list

**2****Description**

Time of hospitalization

**Timepoint**

After interventions

**Method of measurement**

Check list

**3****Description**

Heart function

**Timepoint**

After interventions

**Method of measurement**

Eco cardiography

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: patients in this group, whose thromboembolism has been previously proven by CT scan and Geneva criteria, are visited and evaluated by a cardiology resident and treated if patients are at high risk for thromboembolism, they will be treated according to the protocol provided by the Timar team members and the treatment plan will be implemented within a maximum of 60 minutes. Mortality and treatment complications as well as cardiac function in patients after interventions will be measured by echocardiography and checklist.

### Category

Treatment - Other

## 2

### Description

Control group: patients in this group, as usual and according to hospital protocols, will be examined by a cardiology resident and their thromboembolism will be diagnosed by CT scan and Geneva criteria and will be treated by the cardiology service. Mortality and treatment complications as well as cardiac function in patients after interventions will be measured by echocardiography and checklist.

### Category

Treatment - Other

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Shahid Chamran hospital

#### Full name of responsible person

Mohammad Hadi Mansouri

#### Street address

No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

#### City

Isfahan

#### Province

Isfahan

#### Postal code

8174673461

#### Phone

+98 31 3668 0042

#### Email

mansouri.hadi@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Shaghayegh Haghjoo

### Street address

No. 18, Hezar Jarib Ave., Daneshgah Blvd., Isfahan

### City

Isfahan

### Province

Isfahan

### Postal code

8174673461

### Phone

+98 31 3668 0042

### Email

haghjoo.sh@med.mui.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

#### Full name of responsible person

Mohammad Hadi Mansouri

#### Position

Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Cardiology

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Hadi Mansouri  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Cardiology  
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mansouri.hadi@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Mohammad Hadi Mansouri  
**Position**  
Assistant professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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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

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

All data can be shared after people have requested.

### When the data will become available and for how long

Six months after publishing the results.

### To whom data/document is available

Academic researchers

### Under which criteria data/document could be used

Scientific uses

### From where data/document is obtainable

Website of the Research Committee of Isfahan University of Medical Sciences

### What processes are involved for a request to access data/document

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

### Comments