

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

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Province

Isfahan

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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

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Postal code

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Phone

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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
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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