Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Thrombolytic Therapy Plus Anticoagulant Versus Anticoagulant Alone In Sub Massive Pulmonary Thrombo Embolism: (A Randomized clinical trial)

Protocol summary

Summary

The aim of this study is to compare thrombolytic therapy plus anticoagulant ,versus anticoagulant alone in patients with submassive pulmonary thromboemboli;Patients with acute pulmonary emboli who have ducumented pulmonary emboli in CT angiography with at least one of these criterias:1-Right ventricular dilatation and dysfunction or 2- Pulmonary artery hypertention in echocardiography , are enrolled in our study.Patients are excluded of study if they have : arterial hypotention; left heart or valvular disease ; and contraindication to anticoagulant or thrombolytic. 50 patients with sub massive pulmonary emboli who are admitted in Loghman Hakim hospital enrolled in this study sequentially. Patients randomly assign to receive thrombolytic(Streptokinase 1500000unit or Alteplase 100mg/2 hours) plus Enoxaparine 1mg/kg/2 times a day for one week or only Enoxaparine 1mg/kg/2 times a day for one week. The primary out come is in hospital death or clinical detoriation requiring an escalation of treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042017343N1**
Registration date: **2014-05-18, 1393/02/28**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-05-18, 1393/02/28

Registrant information

Name

Maryam Taherkhani

Name of organization / entity

Shahid Beheshti University of Medical Sciences, Loghman Hakim Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 9005

Email address

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Recruitment status

Recruitment complete

Funding source

Cardiovascular Reaserch Center , Shahid Beheshti University Of Medical Science

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Thrombolytic Therapy Plus Anticoagulant Versus Anticoagulant Alone In Sub Massive Pulmonary Thrombo Embolism: (A Randomized clinical trial)

Public title

Thrombolytic Therapy In Sub Massive Pulmonary Thromo Emboli

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 18 t0 80 years old ;pulmonary thrombo emboli in CT angiography ;right heart involvement in echocardiography;normal bood pressure Exclusion criteria :patients under 18 ;patients

under 80 ; normal echocardiography;left heart disease in echocardiography;arterial hypotention

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Heart Local Ethic Committee Of Loghman Hakim Hospital

Street address
Loghman Hakim Hospital, Makhsos street, South Kargar

City
Tehran

Postal code

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
1162

Health conditions studied

1

Description of health condition studied
Pulmonary Thrombo Emboli

ICD-10 code
I26.0

ICD-10 code description
Pulmonary embolism with mention of acute cor pulmonale

Primary outcomes

1

Description
in-hospital death

Timepoint
during hospitalization

Method of measurement
observation-

2

Description
clinical deterioration that required an escalation of treatment.

Timepoint
during hospitalization

Method of measurement
manometr-blood gas-pulse oximetry

Secondary outcomes

1

Description
Major Bleeding

Timepoint
During Hospitalization

Method of measurement
Hemoglobin Level

2

Description
Right Ventricular Size and Pulmonary Artery Pressure

Timepoint
At The Time Of Discharge

Method of measurement
Echo Cardiology

Intervention groups

1

Description
case group: Enoxaparin 1 milligram per kilogram 2 times a day for 7 days plus thrombolytic(Streptokinase 1500000 unit or Ateplase 100 milligram) in 2 hour

Category
Treatment - Drugs

2

Description
Control group: only Enoxaparine 1 milligram per killogram 2 times aday for one week

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Hospital
Full name of responsible person
Dr Maryam Taherkhani
Street address
Makhsos Street, South Kargart
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
cardiovascular research center,Shahid Beheshti University Of Medical Sience
Full name of responsible person
Miss Vahedi
Street address
Cardiovascular Research Center, Saadat Abad Street, Kaj Squar
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
cardiovascular research center,Shahid Beheshti University Of Medical Sience
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University Of Medical Sciences
Full name of responsible person
Dr Maryam Taherkhani
Position
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty