

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparative efficacy and complications of Two-Hour versus 24-Hour Regimen of Streptokinase in Acute Pulmonary Embolism In Tehran Heart Center

Protocol summary

Summary

This study is a single center randomized controlled clinical trial that seeks to compare conventional medical therapy (24-hours streptokinase) with interventional therapy (2-hours streptokinase) in patients with acute pulmonary emboli. Patients with acute pulmonary emboli are included if written informed consent was filled by patients. Patients are randomized into two groups by blocked randomization. Each group has 30 patients. In both groups treatment is venous streptokinase and then heparin. One of the groups receives streptokinase during 2 hours and another group receives during 24 hours. Streptokinase is a polypeptide derivative from β -hemolytic streptococcus cultivation ambience that adhered to plasminogen and causes formation of active form of plasminogen activator enzyme. CT- angiography and Echocardiography has been done for all patients before treatment starting. Streptokinase is beginning for massive and sub massive pulmonary emboli patients who have unstable hemodynamic (SBp<90 mmHg or deuce systolic Bp more than 40 mmHg) or have intermediate or sever RV dysfunction. Patients with hemorrhagic stroke or ischemic stroke in last 6 months; TIA in last 6 months; Warfarin consumption; pregnancy and persistent hypertension (systolic Bp > 180 mmHg) has streptokinase contraindications. For all patients after streptokinase ending aPTT (activated partial thromboplastin time) is measured. If aPTT will be less than twice the control value, heparin therapy begins.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104245625N2**

Registration date: **2011-08-28, 1390/06/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-28, 1390/06/06

Registrant information

Name

Yaser Jenab

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran Heart Center

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy and complications of Two-Hour versus 24-Hour Regimen of Streptokinase in Acute Pulmonary Embolism In Tehran Heart Center

Public title

streptokinase in acute pulmonary embolism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: streptokinase only begin for massive or submassive pulmonary emboli patients who have these conditions: unstable hemodynamic (systolic blood pressure less than 90 mmHg or reduce systolic blood pressure more 40 mmHg) intermediate or severe RV dysfunction (right ventricle) Exclusion criteria: history of hemorrhagic stroke or unknown origin stroke; Ischemic stroke in past 6 months; central nervous system neoplasm; major trauma, head surgery or injury in past 3 months; TIA attack in past 6 months; oral anticoagulant drugs users; pregnancy or 1st post partum week; traumatic resuscitation; resistant hypertension (systolic blood pressure more than 180 mmHg); progressive liver disease; infected endocarditis; active stomach ulcer;

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Heart Center Ethics Committee

Street address

Tehran Heart Center, North Kargar Ave, Tehran, Iran

City

Tehran

Postal code

1411713138

Approval date

2011-02-28, 1389/12/09

Ethics committee reference number

484

Health conditions studied

1

Description of health condition studied

Acute Pulmonary Embolism

ICD-10 code

I26, I27,

ICD-10 code description

Pulmonary heart disease and diseases of pulmonary circulation

Primary outcomes

1

Description

Pulmonary artery pressure (PAP)

Timepoint

before beginning of streptokinase and 24-72h after treatment beginning

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: in this group patients will be received 1.5 million Units venous streptokinase, infused during 2 hours. Before treatment starting, Echocardiography and CT- angiography achieve for all patients (intervention and control group). Pulmonary artery pressure (PAP) measure by Echocardiography. 24-72h after treatment ending, second Echocardiography will be done. In all patients aPTT measure after streptokinase therapy. If aPTT be less than twice normal value, heparin therapy begins and if be more than this value, this test repeat per 4 hours while become less than twice normal value.

Category

Treatment - Drugs

2

Description

In control group, 250,000 Units bolus Streptokinase infuse during 30 minutes and then 100,000 Units per hour infuse during 24 hours.

Category

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 Ave, Tehran, Iran

City

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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

City

Tehran

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

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

Tehran Heart Center

Full name of responsible person

Dr.Yaser Jenab

Position

Chief Of Emergency Department, assistant Professor

Other areas of specialty/work

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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