Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ambiance that adhered to plasminogen and causes formation of active form of plasmine actuator 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

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Name of organization / entity
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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 sever 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 than180 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 begining of streptokinase and 24-72h after treatment begining
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 30minutes and then 100,000 Units per hour infuse during 24 hours.
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 Ave, Tehran, Iran

City
Tehran

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