

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Catheter directed thrombolysis versus anticoagulation only in patients with Intermediate-high risk pulmonary emboli-A randomized clinical trial

Protocol summary

Study aim

To compare right ventricular dysfunction, clinical deterioration, bleeding, mortality, functional class between catheter directed thrombolysis versus anticoagulation alone in patients with Intermediate- High Risk pulmonary emboli

Design

Randomized, parallel groups, with blinded outcome assessment controlled trial

Settings and conduct

The trial will be held in a hospital setting (Rajaie Cardiovascular Center and Tehran Heart Center) on patients with acute pulmonary emboli. Patients will be randomized via central web based method into intervention and control groups. Patients and physicians are not blinded. Echocardiographic indexes will be recorded on admission and 72 hours later. In follow up period, echocardiography exam and 6-minute walk test for functional class will be performed.

Participants/Inclusion and exclusion criteria

Inclusion: Men and women ≥ 18 year-old, Acute pulmonary emboli must be confirmed with pulmonary CT angiography, Symptoms onset ≤ 14 days, Elevated pro b-type natriuretic peptide and cardiac troponin, Right ventricle/left ventricle ratio in pulmonary CT angiography >0.9 Exclusion: Pulmonary emboli diagnosed with other modalities than pulmonary CT angiography, High risk (massive) pulmonary emboli, Severe renal dysfunction (creatinine clearance below 30 mL/min), Thrombolytic contraindication, Concomitant right heart thrombosis

Intervention groups

The intervention group will receive catheter directed thrombolysis. After femoral vein puncture, an infusion catheter will be inserted to the diseased pulmonary artery and thrombolytic will be started locally. The control group will receive oral anticoagulation according to guideline

Main outcome variables

Primary outcome: Right ventricular function; right

ventricular size; in-hospital deterioration Secondary outcome: Mortality; functional class during follow up; Minor and Major Bleeding

General information

Reason for update

Adding the acronym, and the termination date

Acronym

CANARY

IRCT registration information

IRCT registration number: **IRCT20181022041406N1**

Registration date: **2019-01-27, 1397/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-10, 1400/09/19**

Update count: **2**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Parham Sadeghipour

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2092

Email address

psadeghipour@hotmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2020-02-02, 1398/11/13

Trial completion date

2020-05-02, 1399/02/13

Scientific title

Catheter directed thrombolysis versus anticoagulation only in patients with Intermediate-high risk pulmonary emboli-A randomized clinical trial

Public title

Thrombolysis via catheter in treatment of Pulmonary Emboli

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Men and women ≥ 18 year-old Acute pulmonary emboli must be confirmed with pulmonary CT angiography Symptoms onset ≤ 14 days Elevated pro b-type natriuretic peptide and cardiac troponin Right ventricle/left ventricle ratio in pulmonary CT angiography >0.9 simplified pulmonary embolism severity index score ≥ 1 Less than 48 hours of anticoagulation therapy

Exclusion criteria:

Pulmonary emboli diagnosed with other modalities than pulmonary CT angiography High risk (massive) pulmonary Emboli Segmental pulmonary emboli Patient with terminal illness Surgery within 2 weeks Severe renal dysfunction (creatinine clearance [CrCl] below 30 mL/min) Platelet count <50.000 Thrombolytic contraindication Concomitant right heart thrombosis Pre and post catheter directed thrombolysis echocardiography exam not possible

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **288**Actual sample size reached: **94****Randomization (investigator's opinion)**

Randomized

Randomization description

In the present study, concealment will be central via the website: <http://thcresearch.net>. After entering the username and password by the investigator, the patient ID will be asked by the web-based program. Then by using the permuted block randomization method, each patient (individual) will be assigned to intervention or control group.

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**

Rajaie Cardiovascular Medical and Research Center
Ethic committee

Street address

Vali-Asr ave, Hashemi Rafsanjani Exp

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.RHC.REC.1397.050

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

Pulmonary emboli

ICD-10 code

I26

ICD-10 code description

Pulmonary embolism

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

Right ventricular diameter/left ventricular diameter ratio

Timepoint

3-month after intervention

Method of measurement

Echocardiography

Secondary outcomes**1****Description**

Mortality

Timepoint

During hospitalization and 3-months after intervention

Method of measurement

Questionnaire

2

Description

Minor bleeding

Timepoint

Duration of hospitalization

Method of measurement

Bleeding Academic Research Consortium scale

3

Description

Major bleeding

Timepoint

Duration of hospitalization

Method of measurement

Bleeding Academic Research Consortium scale

4

Description

Right ventricular diameter/left ventricular diameter ratio

Timepoint

72 hours after intervention

Method of measurement

Echocardiography

5

Description

Right ventricular recovery

Timepoint

3 months after intervention

Method of measurement

Echocardiography

Intervention groups

1

Description

Intervention group: The group will receive catheter directed thrombolysis. After femoral vein puncture, an infusion catheter will be inserted to the diseased pulmonary artery and thrombolytic will be started locally.

Category

Treatment - Drugs

2

Description

Control group: The group will receive oral anticoagulation according to guideline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

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2

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Yaser Jenab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center

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Feridoun Nouhi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rajaie Cardiovascular Medical and Research Center
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
Rajaie Cardiovascular Medical and Research Center
Full name of responsible person
Parham Sadeghipour
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Cardiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available