Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of fast versus ultraslow infusion of thrombolytic in patients with mechanical prosthetic valve thrombosis- A randomized controlled trial

Protocol summary

Study aim
Comparison of fast versus ultraslow infusion of thrombolytic regimen in patients with mechanical prosthetic valve thrombosis

Design
Two parallel groups randomized trial with blinded outcome assessment

Settings and conduct
The trial will be held in a hospital setting (Rajaie Cardiovascular Medical and Research center) on patients with mechanical prosthetic valve thrombosis . Patients will be randomized via central web based method into two interventional groups with two different thrombolytic regimen. Treating physician and patients will not be blinded. Thrombus resolution and degree of valve openingwill be evaluated by echocardiography after thrombolytic therapy. Also thrombolytic complication will be evaluated during hospitalization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: provision of signed and dated informed consent form; patients with prosthetic mechanical valve thrombosis approved by echocardiography; men and women ≥ 18 year-old. Exclusion criteria: contraindication of thrombolytic therapy; dyspnea of functional class 4; thrombus size larger than 0.8 cm2.

Intervention groups
In this study there are two interventional groups: first group: patients will receive fast thrombolytic regimen. Second group: patients will receive ultra slow thrombolytic regimen.

Main outcome variables
Degree of valve opening; thrombus size; clinical functional class; bleeding; thromboembolic complications

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181022041406N2**
Registration date: **2019-04-03, 1398/01/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-11, 1400/09/20**
Update count: **1**

Registration date
2019-04-03, 1398/01/14

Registrant information

Name
Parham Sadeghipour

Name of organization / entity
Rajaie Cardiovascular Medical and Research Center

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Iran (Islamic Republic of)

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+98 21 2392 2092

Email address
psadeghipour@hotmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparison of fast versus ultraslow infusion of thrombolytic in patients with mechanical prosthetic valve thrombosis- A randomized controlled trial

Public title
Thrombolytic in mechanical prosthetic valve thrombosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Provision of signed and dated informed consent form Patients with prosthetic mechanical valve thrombosis approved by echocardiography Men and women ≥ 18 year-old
Exclusion criteria:
Contraindication of thrombolytic therapy Dyspnea of functional class 4 Thrombus size larger than 0.8 cm2
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed via permuted block randomization method. Allocation will be generated via a web based system and consequently concealment will be central using computer software. Unit of randomization will be individual patients and no stratification will be applied.
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
2018-06-30, 1397/04/09
Ethics committee reference number
IR.RHC.REC.1397.022

Health conditions studied

1

Description of health condition studied
Mechanical prosthetic valve thrombosis
ICD-10 code
T82.0
ICD-10 code description
Mechanical complication of heart valve prosthesis

Primary outcomes

1

Description
Degree of valve opening
Timepoint
Hospitalization
Method of measurement
Echocardiography

2

Description
Thrombus size
Timepoint
Hospitalization
Method of measurement
Echocardiography

3

Description
Clinical functional class
Timepoint
Hospitalization
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Bleeding
Timepoint
Hospitalization
Method of measurement
CT angiography

2

Description

Thromboembolic events

Timepoint

Hospitalization

Method of measurement

CT angiography

Intervention groups

1

Description

Intervention group: Fast thrombolytic regimen

Category

Treatment - Drugs

2

Description

Intervention group: ultraslow thrombolytic regimen

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie cardiovascular medical and research center

Full name of responsible person

Parham Sadeghipour

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Vali-Asr ave, Hashemi Rafsanjani Exp

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie cardiovascular medical and research center

Full name of responsible person

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 scientific inquiries

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Position

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Person responsible for updating data

Contact
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Full name of responsible person
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Position
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Other areas of specialty/work
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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

Trial results

Please tick if results have been published
Yes
Summary result posting date
2021-12-11, 1400/09/20
Table of baseline comparison
Participant flow diagram
Table of variable outcomes' results
Table of adverse events
First publication date
2021-12-04, 1400/09/13
Abstract of published paper
Background Thrombolysis is an alternative to surgery for mechanical prosthetic valve thrombosis (MPVT). Randomized clinical trials have yet to test safety and efficacy of a proposed ultraslow thrombolytic infusion regimen. Methods and Results This single-center, open-label, pilot randomized clinical trial randomized adult patients with acute obstructive MPVT to an ultraslow thrombolytic regimen (25 mg of recombinant tissue-type plasminogen activator [rtPA] infused in 25h) and a fast thrombolytic regimen (50 mg of rtPA infused in 6h). If thrombolysis failed, a repeated dose of 25 mg of rtPA for 6h was administered in both groups up to a cumulative dose of 150 mg or the occurrence of a complication. Primary outcome was a complete MPVT resolution (>75% fall in the obstructive gradient by transthoracic echocardiography, <10° limitation in opening and closing valve motion angles by fluoroscopy, and symptom improvement). Key safety outcome was a BARC type III or V major bleeding. Overall, 120 patients, including 63 (52.5%) women, at a mean age of 36.3±15.3 years, were randomized. Complete thrombolysis success was achieved in 51 patients (85.0%) in the ultraslow-regimen group and 47 patients (78.3%) in the fast-regimen group (OR, 1.58; 95% CI, 0.25 to 1.63; P = 0.34). One case of transient ischemic attack and 3 cases of intracranial hemorrhage (absolute risk difference, −12.5%; 95% CI, −23.1% to −1.0%; P = 0.04). were observed only in the fast-regimen group. Conclusions The ultraslow thrombolytic regimen conferred a high thrombosis resolution rate without major complications. Such findings should be replicated in more adequately powered trials (IRCT20181022041406N2).