

# 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 opening will 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  $\geq 18$  year-old. Exclusion criteria: contraindication of thrombolytic therapy; dyspnea of functional class 4; thrombus size larger than 0.8 cm<sup>2</sup>.

##### 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

###### 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

2018-07-23, 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  $\geq$  18 year-old

### Exclusion criteria:

Contraindication of thrombolytic therapy  
Dyspnea of functional class 4  
Thrombus size larger than 0.8 cm<sup>2</sup>

## 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  
**Street address**  
Vali-Asr ave, Hashemi Rafsanjani Exp  
**City**  
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**Province**  
Tehran  
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**Email**  
psadeghipour@rhc.ac.ir

## Sponsors / Funding sources

1

**Sponsor**  
**Name of organization / entity**  
Rajaie cardiovascular medical and research center  
**Full name of responsible person**  
Feridoun Nouhi  
**Street address**  
Vali-Asr Ave, Hashemi Rafsanjani Exp  
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fnoohi@rhc.ac.ir

**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  
**Street address**  
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## Person responsible for scientific inquiries

### Contact

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Parham Sadeghipour  
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Assistant professor  
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**Person responsible for updating data****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

**Street address**

Vali-Asr Ave, Hashemi Rafsanjani Exp

**City**

Tehran

**Province****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 thrombolysis resolution rate without major complications. Such findings should be replicated in more adequately powered trials (IRCT20181022041406N2).