

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Comparative analysis of success rate and complications of catheter guided thrombolysis and mechanical thrombectomy with Aspirex Device in patients with acute iliofemoral deep vein thrombosis

#### Protocol summary

##### Summary

This study is aimed to compare success rate and complications of catheter guided thrombolysis and mechanical thrombectomy with Aspirex Device in patients with acute iliofemoral DVT. In this clinical trial study, 20 patients aged less than 60 years old with the onset of symptoms less than 2 weeks, referred to Razi hospital in Rasht, and initial diagnosis of acute iliofemoral deep vein thrombosis made by Doppler ultrasound and definite diagnosis made by venography, are included. Patients with heart, renal or pulmonary failure; and the patients with the diagnosis of DVT after two weeks of symptoms' onset are excluded. In this single blinded study patients are randomly (random numbers) divided to two groups of catheter guided thrombolysis and mechanical thrombectomy with Aspirex Device. Patients' information including age; sex; underlying disease; affected side; primary symptoms (pain; tenderness; swelling; palor; and ...); timeline of the treatment; success rate of the treatment; duration of hospitalization; complications during treatment and hospitalization, complete lysis; improvement of the primary symptoms; and the need of further treatment (stenting or balloon angioplasty), will be recorded in the checklists. Primary outcomes: Duration of treatment and the success rate of the treatment Secondary outcomes: Duration of hospitalization, Complication during treatment, Complete thrombolysis, Improvement of the primary symptoms, Complications during hospitalization

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016102630508N1**

Registration date: **2016-12-16, 1395/09/26**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-12-16, 1395/09/26

##### Registrant information

###### Name

Hosein Hemmati

###### Name of organization / entity

Vascular surgery and dialysis research center, Guilan University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 3354 2460

###### Email address

hemmati@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Guilan University of Medical Sciences

##### Expected recruitment start date

2016-10-15, 1395/07/24

##### Expected recruitment end date

2017-10-16, 1396/07/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative analysis of success rate and complications of catheter guided thrombolysis and mechanical thrombectomy with Aspirex Device in patients with acute iliofemoral deep vein thrombosis

## Public title

Treating acute ileofemoral DVT by mechanical thrombectomy with Aspirex Device

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: all the patients aged less than 60 years old with the onset of symptoms less than 2 weeks that initial diagnosis of acute ileofemoral deep vein thrombosis has been made by Doppler ultrasound and definite diagnosis has been made by venography and are a candidate for treatment Exclusion criteria: patients with heart, renal or pulmonary failure; and the patients with the diagnosis of DVT after two weeks of symptoms onset

## Age

To 60 years old

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 20

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

randomized by random number

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

##### Street address

Opposite Sepah Bank, Western Shahid Beheshti Blvd., Gaz Square

##### City

Rasht

##### Postal code

41448-95655

#### Approval date

2016-10-15, 1395/07/24

#### Ethics committee reference number

IR.GUMS.REC.1395.218

## Health conditions studied

### 1

#### Description of health condition studied

Deep vein thrombosis

#### ICD-10 code

180.2

#### ICD-10 code description

Deep vein thrombosis NOS

## Primary outcomes

### 1

#### Description

Duration of the treatment

#### Timepoint

During hospitalization

#### Method of measurement

The time recorded in the checklist

### 2

#### Description

The success rate of the treatment

#### Timepoint

During hospitalization after treatment

#### Method of measurement

venography

## Secondary outcomes

### 1

#### Description

Duration of hospitalization

#### Timepoint

During hospitalization

#### Method of measurement

The time recorded in the checklist

### 2

#### Description

Complications during the treatment

#### Timepoint

During treatment

#### Method of measurement

Physical examination and Lab tests

### 3

#### Description

Complete Thrombus lysis

#### Timepoint

During hospitalization after treatment

#### Method of measurement

Venography

#### 4

##### **Description**

Improvement of the primary symptoms

##### **Timepoint**

During hospitalization, 2 weeks, 1 month, 45 days and 6 months after intervention

##### **Method of measurement**

Physical examination

#### 5

##### **Description**

Complications during hospitalization

##### **Timepoint**

During hospitalization

##### **Method of measurement**

Physical examination and Lab tests

### **Intervention groups**

#### 1

##### **Description**

control group: Catheter guided thrombolysis. Prior to thrombolysis all patients will be given heparin 1000 U/h. PTT will be evaluated and heparin dose will be adjusted based on patient's PTT. While the patients are on strict bed rest and anti-coagulation, catheter will be introduced into the thrombus and alteplase infusion will be started with the dose of 1 mg/h. After 48h a control venography will be performed to evaluate the progress; if there be an underlying stenotic lesion, balloon angioplasty and stenting will be performed as a supplementary procedure.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Intervention group: mechanical thrombectomy with Aspirex Device. Prior to thrombolysis all patients will be given heparin 1000 U/h. PTT will be evaluated and heparin dose will be adjusted based on patient's PTT. While the patients are on strict bed rest and anti-coagulation, Aspirex Device catheter will be introduced into the lumen and will evacuate the thrombus mass through creating active negative pressure, leading to removal of the thrombus. After 48h, a control venography will be performed to evaluate the progress. If there is an underlying stenotic lesion, balloon angioplasty and stenting will be performed as a supplementary procedure.

##### **Category**

Treatment - Devices

### **Recruitment centers**

#### 1

##### **Recruitment center**

**Name of recruitment center**

Razi hospital

##### **Full name of responsible person**

Dr, Maziar Moayeri Far (Resident)

##### **Street address**

Razi hospital, Sardar Jangal Street, Rasht, Guilan

##### **City**

Rasht

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

##### **Name of organization / entity**

Vice Chancellor for research of Guilan University of Medical Sciences

##### **Full name of responsible person**

Dr Shadman Nemati

##### **Street address**

Vice Chancellor for research, west shahid Beheshti Blvd. Rasht, Guilan

##### **City**

Rasht

##### **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 of Guilan University of Medical Sciences

##### **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**

Vascular surgery and Dialysis research center

##### **Full name of responsible person**

Dr Maziar Moayeri Far

##### **Position**

Co worker/ resident

##### **Other areas of specialty/work**

##### **Street address**

Razi hospital, Sardar Jangal Street, Rasht, Guilan

##### **City**

Rasht

##### **Postal code**

4144895655

##### **Phone**

+98 13 3354 2460

**Fax**

**Email**

sedi.3d@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Vascular surgery and Dialysis research center

**Full name of responsible person**

Dr. Hossein Hemmati

**Position**

Associated Professor of vascular Surgery

**Other areas of specialty/work**

**Street address**

Razi hospital, Sardar Jangal Street, Rasht, Guilan

**City**

Rasht

**Postal code**

4144895655

**Phone**

+98 13 3354 2460

**Fax**

**Email**

drhossein\_hemmati@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Vascular surgery and Dialysis research center

**Full name of responsible person**

Dr Maziar Moayeri Far

**Position**

co worker/ resident

**Other areas of specialty/work**

**Street address**

Razi hospital, Sardar Jangal Street

**City**

Rasht

**Postal code**

**Phone**

+98 13 3354 2460

**Fax**

**Email**

sedi.3d@gmail.com

**Web page address**

## 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*