

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

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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

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Person responsible for scientific inquiries

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Name of organization / entity

Vascular surgery and Dialysis research center

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Position

Associated Professor of vascular Surgery

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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