Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Comparative analysis of success rate and complications of catheter guided thrombolysis and mechanical trombectomy with Aspirex Device in patients with acute ileofemoral 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 ileofemoral 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 ileofemoral 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 outcoms: 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
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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 trombectomy with Aspirex Device in patients with acute ileofemoral deep vein thrombosis

Public title
Treating acute ileofemoral DVT by mechanical trombectomy 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 manoths 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 goup: 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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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