Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effect of conventional therapy (Heparin followed by warfarin) with imterventional therapy (thrombolysis with or without angioplasty and stenting) on venous patency in patients who admitted with acute iliofemoral DVT in Tehran Heart Center emergency department

Protocol summary

Summary

This study is a single center randomized controlled clinical trial that seeks to compare conventional medical therapy (heparin followed by warfarin) with multimodality therapy (lytic therapy with or without percutaneous transluminal angioplasty [PTA] and stenting) in patients with acute iliofemoral thrombosis. Patients with acute extensive iliofemoral venous thrombosis are included if written informed consent was filled by patient. On admission patients will be evaluated by MDCT venography. Patient who has contraindications to lytic and anticoagulation therapy; allergic reaction to contrast agents; patients with survival of less than one year; severe renal failure (GFR<30) ; history of SAH or ICH will be excluded. Then patients are randomized into two groups by block randomization. Our study sample size was 15 in each group and totally 30patients. Conventional treatment will consist of intravenous heparin followed by warfarin. The heparin dose will be adjusted to achieve an activated partial thromboplastin time (aPTT) of twice the control value. Heparin will be given for 5 to 7 days. Warfarin will be initiated within 48 to 72 hours and will be continued as standard guidelines. In intervention group thrombolytic agent will be streptokinase and concomitantly, heparin will be administered and continued until therapeutic anticoagulation with warfarin will be accomplished. In addition to regional lytic therapy due to lesion situation percutaneous transluminal angioplasty [PTA] and stenting will be performed. All patients will be followed by routine venous duplex imaging at 30 days, and 1 year follow-up. Also MDCT venography will be performed on admission and six months after discharge in all patients. Thrombus score, lysis grade and patients' symptom will be compared in these two groups by standard classification.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108035625N3**
Registration date: **2011-08-13, 1390/05/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-08-13, 1390/05/22

Registrant information

Name
Yaser Jenab
Name of organization / entity
Tehran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8802 9600
Email address
jenab@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran Heart Center

Expected recruitment start date

2011-08-06, 1390/05/15

Expected recruitment end date

2013-06-05, 1392/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effect of conventional therapy (Heparin followed by warfarin) with imterventional therapy (thrombolysis with or without angioplasty and stenting) on venous patency in patients who admitted with acute iliofemoral DVT in Tehran Heart Center emergency department

Public title
Traditional medical treatment versus interventional approach in acute iliofemoral vein thrombosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Consecutive patients with acute extensive iliofemoral venous thrombosis will be included. Exclusion criteria: previous history of allergy to thrombolytic or contrast agents; anticoagulation contrandications; bleeding disorders, active internal bleeding, recent gastrointestinal bleeding, recent cerebrovascular accident, recent major surgery (<10 days), recent serious trauma, severe hypertension, pregnancy or recent delivery, metastatic malignancy with central nervous system involvement, chronic iliofemoral venous thrombosis (more than 14 days from incidence);patients with survival of less than 1 year; severe renal failure (GFR<30); history of subarachnoid hemorrhage (SAH) or intra cranial hemorrhage (ICH)
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Tehran Heart Center ethics committee
Street address
Tehran Heart Center, North Kargar street and Jalal Al Ahmad cross
City
Tehran
Postal code
1411713138
Approval date
2011-07-25, 1390/05/03
Ethics committee reference number
508

Health conditions studied

1

Description of health condition studied
Acute liofemoral veins thrombosis
ICD-10 code
I82
ICD-10 code description
other venous embolism and thrombosis

Primary outcomes

1

Description
Venous patency
Timepoint
One, six and twelve months follow up
Method of measurement
Doppler ultra sonography and MDCT venography

Secondary outcomes

1

Description
Symptom changes (pain,edema,varices,...)
Timepoint
One, six and twelve months follow up
Method of measurement
Clinical evaluation

Intervention groups

1

Description
Intervention: lytic therapy will be achieved by placing a catheter in the contralateral femoral vein, the right internal jugular vein, or the ipsilateral popliteal vein for direct intra-clot infusion. An attempt will be made to cross the thrombosed vein with a 0.035-inch guide wire. Once the guide wire crossed the thrombus, multiple side-hole catheters will be advanced into the thrombus to assure maximum delivery of the lytic agent. Streptokinase will be given as a loading dose of 250,000

units followed by infusion of 100,000 units per hour for 24 to 48 hours. Heparin will be administered concomitantly with the lytic therapy and continued until therapeutic anticoagulation with warfarin will be accomplished. aPTT levels will be obtained before and every 12 hours after thrombolytic therapy has been started. Effect of treatment will be assessed daily by venography.Thrombus lysis will be quantified by using thrombus lysis score. Therapy will be continued until maximum lysis will be achieved. After lytic therapy, further intervention (PTA/stenting) will be performed if there is an underlying venous stenosis of 50% or more. Stent placement will be done with appropriate selected stents (self-expanding stainless steel wall stents). All stented patients will be given warfarin indefinitely (INR 2–3). Lysis will be considered complete if there is less than 5% residual thrombus.

Category

Treatment - Drugs

2

Description

Control: conventional treatment will consist of intravenous heparin followed by warfarin. A loading dose of 5,000 to 10,000 units heparin followed by 1,000 to 2,000 units per hour will be given by continuous intravenous infusion. The dose will be adjusted to achieve an activated partial thromboplastin time (aPTT) of twice the control value. Heparin will be given for 5 to 7 days. Warfarin will be initiated within 48 to 72 hours and will be continued as standard guidelines. The warfarin dose will be adjusted to achieve a prothrombin time of 1.5 to 2 times control or an international normalized ratio (INR) of 2 to 3. All patients will be treated with limb elevation and moist heat during their initial admission and maintained on prescription gradient compression stockings.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Dr Yaser Jenab

Street address

North Kargar and Jalal Al Ahmad cross

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research,Tehran Heart Center (TUMS)

Full name of responsible person

Dr Saeed Sadeghian

Street address

North kargar and Jalal Al Ahmad cross

City

Tehran

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,Tehran Heart Center (TUMS)

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

Tehran Heart Center

Full name of responsible person

Dr.Neda Ghaffari-Marandi

Position

M.D./Researcher

Other areas of specialty/work

Street address

North Kargar and Jalal Al Ahmad cross

City

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

+98 21 8802 9256

Email

ghaffari_15255@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran Heart Center

Full name of responsible person

Dr. Yaser Jenab

Position

M.D. /Assistant professor of cardiology

Other areas of specialty/work

Street address

North Kargar and Jalal Al Ahmad cross

City

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

+98 21 8802 9600

Email

jenab@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran Heart Center

Full name of responsible person

Dr. Neda Ghaffari-Marandi

Position

M.D./Researcher

Other areas of specialty/work

Street address

North kargar and Jalal Al Ahmad cross

City

Tehran

Postal code

1411713138

Phone

+98 21 8802 9600

Fax

+98 21 8802 9256

Email

ghaffari_15255@yahoo.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