ISRCTN69393729 https://doi.org/10.1186/ISRCTN69393729

Surgical treatment for acute severe venous thrombosis and edema of the left lower extremity

Submission date
03/10/2025

Recruitment status
No longer recruiting

Registration date
12/10/2025

Overall study status
Completed

Last Edited
06/10/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with left iliac vein compression combined with iliofemoral venous thrombosis are at high risk of developing post-thrombotic syndrome. Previous studies have shown that thrombus debulking during the acute phase can reduce the incidence of post-thrombotic syndrome (PTS), but there is currently no consensus on the specific procedures for thrombus debulking. This study aims to evaluate the impact of two main thrombus debulking strategies, Pharmacomechanical Thrombectomy (PMT) and PMT+Catheter-Directed Thrombolysis (CDT), on patient outcomes, and to determine whether PMT alone is as safe and effective as PMT+CDT.

Who can participate?
Patients aged 18 years or older with left iliac vein compression combined with acute left iliofemoral venous thrombosis, who meet the inclusion and exclusion criteria and require surgical intervention.

What does the study involve?
Patients will be randomly assigned to either the PMT group or the PMT+CDT treatment group. The study will primarily focus on the immediate thrombus debulking efficacy after surgery, perioperative complications, cost-effectiveness, and patient-reported quality of life during follow-up. Follow-up visits will be conducted every 3 months within the first year after surgery, and then annually thereafter.

What are the possible benefits and risks of participating?
There are no additional benefits or risks from participating in this study, as both surgical techniques are already routinely used in the study centre.

Where is the study run from?
Beijing Luhe Hospital, Capital Medical University, China

When is the study starting and how long is it expected to run for?
July 2021 to December 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Liu, 380693113@qq.com

Contact information

Type(s)
Public, Principal investigator

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Scientific

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Study information

Scientific Title
Does combined catheter-directed thrombolysis after mechanical thrombectomy reduce the risk of post-thrombotic syndrome in acute left iliofemoral venous thrombosis?

Study objectives
To explore the risk factors for poor prognosis and establish strategies to improve prognosis in left iliac vein compression combined with acute left iliofemoral deep vein thrombosis by analyzing the thrombus reduction on prognosis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/11/2023, Medical Ethics Committee of Beijing Luhe Hospital, Capital Medical University (82 Xinhua South Road, Beijing, 101149, China; +86 (0)1069543901; lhyyllwyh@163.com), ref: 2023-LHKY-118-02

Study design
Single-center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Thrombus debulking therapy for patients with iliac vein compression combined with deep vein thrombosis.

Interventions
Patients who meet the inclusion and exclusion criteria will be randomly assigned using a computer program to the Pharmacomechanical Thrombectomy (PMT) group or the PMT+Catheter-Directed Thrombolysis (CDT) group, and the thrombus debulking efficacy in the left lower extremity deep veins and differences in PTS-related outcomes between the two groups will be compared.

In the PMT group, the AngioJet thrombectomy system will be used to locally spray urokinase and remove thrombus. The PMT+CDT group will receive catheter-directed thrombolysis (CDT) following PMT; specifically, a thrombolytic catheter will be placed at the center of the thrombus, followed by continuous local infusion of urokinase and heparin.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Complications measured using the Villalta score and the revised Venous Clinical Severity Score (r-VCSS) at 2 years

Key secondary outcome(s))
1. Duration of surgery measured using patient records
2. Duration of bed rest measured using patient records
3. Perioperative blood loss (in milliliters), quantitatively measured in mL, measured using patient records
4. Percentage (%) of bleeding events during the surgical and thrombolytic periods measured using patient records
5. Incidence rate of intraoperative complications (%): the percentage (%) of patients experiencing any intraoperative complication measured using patient records during the procedure
6. Immediate thrombus debulking outcome measured using the venous luminal patency score at

the end of the intraoperative debulking procedure
7. Incidence of post-thrombotic syndrome (PTS) measured periodically using the Villalta score during the 2-year follow-up period
8. Quality of life measured periodically using the revised Venous Clinical Severity Score (r-VCSS) during the 2-year follow-up period
9. Reflux of the femoral vein valves, measured by lower extremity venous Doppler ultrasound during regular follow-up visits within 2 years
10. Recurrence of lower extremity venous thrombosis or iliac vein occlusion, measured by lower extremity venous Doppler ultrasound during regular follow-up visits within 2 years
11. Cost-effectiveness measured using hospitalization costs within 30 days postoperatively

Completion date
01/10/2025

Eligibility

Key inclusion criteria
1. Age between 18 and 80 years
2. Definitively diagnosed with iliofemoral venous thrombosis of the left lower extremity by color Doppler ultrasound
3. Time from symptom onset to initiation of treatment was less than 14 days
4. Diagnosed with LIVC by color Doppler ultrasound or CTV (CT venography)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
304

Key exclusion criteria
1. History of deep vein thrombosis in the left lower extremity
2. Time from symptom onset to initiation of treatment exceeds 14 days
3. Local anatomical alterations of the iliac vein, such as lumbar vertebral developmental anomalies, abdominal or pelvic adhesions, space-occupying lesions, or retroperitoneal pathology

Date of first enrolment
29/11/2023

Date of final enrolment
30/12/2023

Locations

Countries of recruitment
China

Study participating centre
Beijing Luhe Hospital, Capital Medical University
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Sponsor information

Organisation
Beijing Luhe Hospital Affiliated to Capital Medical University

ROR
https://ror.org/01zyn4z03

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and analyzed during the current study will be made available on request to Liu D, 380693113@qq.com

IPD sharing plan summary

Available on request