

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

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| Submission date 03/10/2025 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 12/10/2025 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 06/10/2025 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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

Contact name

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Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

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; lhyllwyh@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

82 Xinhua South Road

Beijing

China

101149

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

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|-------------------------------|--------------|------------|----------------|-----------------|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |