

Using artificial intelligence to predict the risk of blood vessel re-narrowing after treatment in people with blocked arteries in the legs

Submission date 14/10/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 15/10/2026	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 15/10/2026	Condition category Circulatory System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Scientific, Public

Contact name
Dr Jing Li

ORCID ID
<https://orcid.org/0009-0009-8191-7251>

Contact details
No. 99 Longcheng Street, Xiaodian District
Taiyuan
China
030032
+86 13994247485
lijing_7112@163.com

Additional identifiers

Study information

Scientific Title
Prediction of oneyear restenosis risk among patients with lower extremity arteriosclerosis obliterans receiving interventional therapy: comparing support vector machine with SHapley

Additive explanations interpretability against Knearest neighbor, neural network and discriminant prediction models for model discrimination, calibration and individual level risk factor attribution

Study objectives

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 10/10/2023, Shanxi Bethune Hospital (Shanxi Academy of Medical Sciences) (No. 99 Longcheng Street, Xiaodian District, Taiyuan, 030032, China; +86 0351-8368114; lijing@sxbqeh.com.cn), ref: [2022] Lun Shen Medical Device No. (12)

Primary study design

Observational

Secondary study design

Cohort study

Study type(s)

Health condition(s) or problem(s) studied

Prediction of postinterventional restenosis in patients with lower extremity arteriosclerosis obliterans

Interventions

This is a retrospective observational cohort study. Researchers will collect and extract existing electronic medical record data from participants diagnosed with lower extremity arteriosclerosis obliterans (LEASO) who received interventional therapy. Collected data will cover demographics, clinical characteristics, lesion related indicators, comorbidities, smoking status, and postoperative medication adherence.

All participants will receive routine clinical interventional therapy selected according to lesion location and severity, including percutaneous transluminal angioplasty, arterial atherectomy, or endovascular stent angioplasty. After the procedure, participants will receive standard postoperative anticoagulant therapy, antiplatelet therapy, circulation improving treatment, as well as guidance for medication and lifestyle modification as per clinical practice. No study specific interventions or control groups will be assigned.

Participants will undergo scheduled followup assessments every 3 months for 1 year after the intervention. Outcome evaluation will be performed via outpatient review, telephone followup, and computed tomography angiography (CTA). Investigators will assess whether participants develop restenosis, defined as $\geq 50\%$ luminal stent stenosis on CTA or recurrent limb symptoms with hemodynamically significant stenosis confirmed by vascular ultrasound or CTA.

The collected dataset will be randomly split into a training set and a validation set at a 7:3 ratio. Multivariable logistic regression will screen risk factors. Four machine learning algorithms

(support vector machine, Knearest neighbor, neural network, discriminant model) will build prediction models with tenfold crossvalidation for internal performance evaluation. SHAP analysis will be applied to interpret feature importance of the optimal prediction model.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Restenosis within 1year after interventional therapy for lower extremity arteriosclerosis obliterans measured using computed tomography angiography (CTA), vascular ultrasound, outpatient review and telephone followup. Restenosis is defined as either CTA demonstrating $\geq 50\%$ luminal stent stenosis, or recurrent intermittent claudication/resting pain of the affected limb together with hemodynamically significant stenosis confirmed by vascular ultrasound or CTA. Medical record data are extracted for outcome adjudication at 12months after interventional therapy

Key secondary outcome(s)

Completion date

30/12/2025

Eligibility

Key inclusion criteria

1. Aged ≥ 18 years
2. Diagnosis of lower extremity arteriosclerosis obliterans (LEASO) confirmed by digital subtraction angiography or computed tomography angiography
3. Received interventional therapy for LEASO
4. Written informed consent obtained from the patient or their family member after study explanation

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

100 Years

Sex

All

Total final enrolment

205

Key exclusion criteria

1. Previous history of lowerlimb vascular bypass surgery or interventional therapy
2. Cognitive impairment or psychiatric disease
3. Lactation or pregnancy status
4. Acute myocardial infarction, cerebral hemorrhage or cerebral thrombosis within the preceding 3months
5. Coagulation dysfunction
6. Autoimmune disease
7. Malignant tumor

Date of first enrolment

25/12/2022

Date of final enrolment

25/12/2025

Locations

Countries of recruitment

China

Sponsor information

Organisation

Shanxi Bethune Hospital (Shanxi Academy of Medical Sciences)

Funder(s)

Funder type**Funder Name**

Science Foundation of Shanxi Bethune Hospital

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not expected to be made available