

Angioplasty With Shockwave IVL Catheter System in Femoropopliteal Lesions

NCT06713850

Status	RECRUITING
Sponsor	Liyuan Hospital of Tongji Medical College, Huazhong University of Science and Technology
Enrollment	130 participants

Key Eligibility Criteria

Inclusion (4)

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- \) Age e 18 years (2) Rutherford Classification 2-5 (3) Stenosis ($\geq 70\%$ stenosis confirmed by digital subtraction angiography (DSA) imaging) or occlusion of the femoropopliteal artery, with one healthy patent outflow tract distal to the knee in continuity with a patent outflow tract below the ankle.
- (4) Patients who understand the purpose of the study, participate in the experiment voluntarily, sign the informed consent form and are willing to be followed up.
- \) The guidewire needs to pass through the lesion; (6) Life expectancy ≥ 24 months (7) Moderately severe calcified lesions confirmed by imaging data; (8) For patients who receive intervention in both lower extremities may be enrolled in order of time of intracavitary treatment (9) For combined aortoiliac artery lesions that have undergone endoluminal revascularization to achieve flow recanalization without more than 50% residual stenosis.

Exclusion (2)

- Patients with stroke, cerebral hemorrhage, gastrointestinal hemorrhage, or cardiac infarction within 3 months prior to enrollment
- (2) Patients with known allergy to heparin, aspirin, other antiplatelet drugs, contrast agents, etc.
- \) Patients who have been enrolled in medications that interfere with this clinical trial within the last 3 months or who have been treated intraoperatively with other special vascular bed preparation devices, such as plaque volume reduction devices, special balloons, and so on; (4) Pregnant and lactating women (5) Patients who are unable or unwilling to participate in this trial. (6) patients with Berger's disease (7) patients who have received arterial bypass diversion on the treated side

Locations (1 total)

Liyuan Hospital of Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei, China