

TP03HN106 in Patients With Critical Limb Ischemia

NCT06482892

Status	RECRUITING
Phase	Phase 2
Sponsor	Talengen Institute of Life Sciences, Shenzhen, P.R. China.
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (7)

- When signing the informed consent form, the age should be \geq 18 years old, regardless of gender;
- Clinically diagnosed as a patient with Critical limb ischemia, with a Rutherford score of 4-6.
- Patients who are unable to undergo interventional surgical treatment, or whose previous interventional surgical treatment is ineffective, or who are unwilling to undergo any intervention or surgical treatment, and can only receive conventional antiplatelet and vasodilator drugs (before baseline, antiplatelet and vasodilator drugs must be used for at least 1 week);
- During the screening period, lower limb artery color ultrasound or lower limb computed tomography angiography (CTA) showed severe stenosis or occlusion of one or more of the common iliac artery, external iliac artery, common femoral artery, superficial femoral artery, popliteal artery, anterior tibial artery, posterior tibial artery, and fibular artery;
- During the screening period, if there are severe symptoms of lower limb ischemia, meeting any of the following symptoms is sufficient: There is limb rest pain caused by lower limb ischemia, with a disease duration of \geq 2 weeks, and a VAS score of \geq 40mm and $<$ 100mm before the first administration; There are limb tissue ulcers caused by lower limb ischemia, with a disease duration of \geq 2 weeks and limb ulcers (4cm² d maximum single ulcer area d 25cm²);

... and 2 more (see full listing online)

Exclusion (14)

- Subjects who are known to be allergic to the investigational drug, its excipients, or other human blood products;
- Patients with limb gangrene greater than 4 cm²;
- Patients currently suffering from malignant tumor diseases (including those who have previously had malignant tumors but have not been cured);
- Screening period for patients with liver and kidney failure:
- Patients who require hemodialysis;

... and 9 more (see full listing online)

Locations (1 total)

The First Affiliated Hospital of Soochow University, Suzhou, Jiangsu, China