Safety and Preliminary Efficacy of Allogeneic Endothelial Progenitor Cells (EPCs) in Patients With Critical Limb Ischemia

NCT06359912

Status	RECRUITING
Phase	Phase 1
Sponsor	Allife Medical Science and Technology Co., Ltd.
Enrollment	27 participants

Key Eligibility Criteria

Inclusion (8)

- CLI patients fulfilling all the following criteria are considered suitable for inclusion in the study.
- Age is between 18 and 80.
- Diagnosis of critical limb ischemia, no surgery or interventional therapy, or poor results one month after interventional therapy (no relief of symptoms), Rutherford grade 3, grade 4 or grade 5, while meeting one of the following criteria: 1) severe intermittent claudication; 2) resting pain; 3) ABId 0.60;
- Within the last month, Digital Subtraction Angiography (DSA), Computed Tomography Arteriography (CTA), Magnetic Resonance Angiography (MRA) or vascular ultrasound has confirmed that one or more of the arteries (superficial femoral artery, i.e., the femoral artery below the deep femoral artery branch, the popliteal artery, and its following arteries) have a stenosis of e70% or occlusion;
- The degree of skin ulcer is determined according to Wagner, grade less than or equal to 4;

... and 3 more (see full listing online)

Exclusion (18)

- Subjects who have received other cell therapies previously
- Subjects who have received or are attending any other unlisted clinical study drug or treatment within 4 weeks prior to the first dose;
- Stenosis of e75% in the main-iliac artery;
- Subjects whose Feet or lower limb infections are uncontrollable, or other uncontrolled active infections;
- Patients with diabetic proliferating retinopathy (diabetic retinopathy grade 4 according to the International Clinical Classification Standard for diabetic retinopathy)

... and 13 more (see full listing online)

Locations (1 total)

Hui Shi, Beijing, Beijing Municipality, China