

Umbilical Cord Artery-derived Perivascular Stem Cells for the Critical Limb Ischemia Therapy

NCT06174597

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Nanjing University
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (7)

- Aged between 18 and 80, of any gender;
 - Diagnosed with lower extremities ischemia, classified as Rutherford Stage IV-V, affecting at least one limb. If both lower limbs have ischemic disease, the researcher will determine which affected limb will be studied. The resting ankle systolic pressure (dorsalis pedis artery or posterior tibial artery) of the affected limb is less than 60mmHg, or the toe systolic pressure is less than 40 mmHg, or the Ankle-Brachial Index (ABI) is less than 0.50;
 - 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 e75% or occlusion;
 - Patient experiences rest pain in the limb due to ischemia for at least two weeks;
 - Inoperable or not suitable for endovascular treatment or no obvious improvement after surgical treatment;
- ... and 2 more (see full listing online)

Exclusion (11)

- Acute ischemic disease of the lower limb(s) occurred within the past 2 weeks, or patients with acute progression of lower extremity arterial ischemic disease, or those with local/diffuse gangrene;
 - Unsatisfactory evaluation of condition stability after vascular reconstruction surgery or sympathetic nerve removal surgery performed within 4 weeks or possibility of undergoing amputation in the next 4 weeks;
 - Stenosis of e75% in the main-iliac artery;
 - Diabetic patients with HbA1c \geq 10%;
 - Abnormal laboratory test results that meet any of the following criteria:i. Abnormal blood routine examination: Hemoglobin (HGB) $<$ 80 g/L, or white blood cell count (WBC) $<$ 3.0×10^9 /L, or platelet count (PLT) $<$ 50×10^9 /L; ii. Abnormal liver function: Aspartate aminotransferase (AST) $>$ 2 times the upper limit of normal (ULN), or alanine aminotransferase (ALT) $>$ 2xULN, total bilirubin (TBIL) $>$ 2xULN; iii. Severe renal dysfunction requiring dialysis treatment;iv. Other abnormal laboratory testing indicators that researchers believe may affect the evaluation of trial results;
- ... and 6 more (see full listing online)

Locations (1 total)

The affiliated Drum Towel Hospital of Nanjing University Medical School, Nanjing, Jiangsu, China

<https://clinicaltrials.gov/study/NCT06174597>

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