

Efficacy and Safety of Stempeucel® in Patients With Critical Limb Ischemia (CLI) Due to Buerger's Disease

NCT05854615

Status	RECRUITING
Phase	Phase 4
Sponsor	Cell Biopeutics Resources Sdn Bhd
Enrollment	3 participants

Key Eligibility Criteria

Inclusion (5)

- Males or females (willing to use accepted methods of contraception during the course of the study) in the age group of 18-65 years.
- Buerger's disease as diagnosed by Shionoya criteria
- Patients should have at least one ulcer (target ulcer): area between 0.5 to 10 cm² (both inclusive)
- Ankle Brachial Pressure Index (ABPI) \geq 0.6. If ABPI is \leq 1.1 then Toe Brachial Index (TBI) will be performed and TBI should be \geq 0.5
- Patients who are able to understand the requirements of the study, and willing to provide voluntary written informed consent, abide by the study requirements, and agree to return for required follow-up visits

Exclusion (4)

- Patients diagnosed with atherosclerotic peripheral arterial disease
- Patients eligible for surgical or percutaneous revascularization
- Patients with a history of participating in another stem cell trial or therapy within 3 months
- Patients who are unsuitable to participate the clinical trial as determined by investigators

Locations (1 total)

Hospital Canselor Tunku Mukhriz, Kuala Lumpur, Malaysia