

Efficacy and Safety of Cold Atmospheric Plasma Combined With Endovascular Intervention for Diabetic Foot Ulcers With Lower Extremity Arterial Occlusion

NCT07198061

Status	RECRUITING
Phase	Not Applicable
Sponsor	Shenyang Medical College
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (4)

-)Age between 18 and 80 years; diagnosed with type 1 or type 2 diabetes mellitus; with HbA1c $\geq 10\%$;
-)Presence of at least one chronic foot ulcer persisting for ≥ 3 weeks, with no signs of healing despite guideline-directed standard care; ulcer classified as Wagner-Armstrong grade 1D or 2D;
-)Imaging-confirmed infrapopliteal arterial stenosis or occlusion, assessed by vascular ultrasound and/or computed tomography angiography (CTA); all patients must have undergone infrapopliteal balloon angioplasty, with successful target vessel revascularisation confirmed intraoperatively ($\geq 30\%$ residual stenosis);
-)Signed written informed consent prior to study participation.

Exclusion (8)

-)Concurrent use of negative pressure wound therapy (NPWT) or maggot debridement therapy;
-)Undergoing dialysis for end-stage renal disease;
-)Use of topical antibiotics with known biological activity on the wound;
-)Use of platelet-rich fibrin (PRF) for wound treatment;
-)Women of childbearing potential without effective contraception, or currently breastfeeding;
- ... and 3 more (see full listing online)

Locations (1 total)

Ansteel Group General Hospital, Anshan, Liaoning, China