

A Prospective Clinical Study to Evaluate the Effectiveness and Safety of Xcell Amnio Matrix™ (XAM) in the Management of Chronic Non-healing DFUs

NCT07116174

Status	RECRUITING
Phase	Not Applicable
Sponsor	New Horizon Medical Solutions
Enrollment	135 participants

Key Eligibility Criteria

Inclusion (23)

- Subjects will be eligible for enrollment in the study only if they meet ALL the following criteria at time of Screening:
 - Subject is 18 years of age or older.
 - Subject has diabetes mellitus (Type 1 or Type 2), requiring insulin or oral/injectable medications to control blood glucose levels
 - Glycosylated hemoglobin (HbA1c) level is $\leq 12\%$
 - Note: Prior documented HbA1c within 12 weeks of Screening is acceptable.
- ... and 18 more (see full listing online)

Exclusion (23)

- Subjects meeting ANY of the following criteria at time of Screening will be excluded from enrollment:
 - Clinical evidence of ongoing infection and/or receipt of IV, oral, or topical antimicrobials.
 - Wheelchair bound or bed-ridden (ambulatory with assistance is acceptable).
 - Ulceration at the site of amputation.
 - Undergoing renal dialysis.
- ... and 18 more (see full listing online)

Locations (3 total)

Limb Preservation Platform, Inc., Fresno, California, United States
North Park Podiatry, San Diego, California, United States
Richard C. Galperin, Dallas, Texas, United States