

Effect of Amnio-Maxx on the Healing Rate of Chronic Diabetic Foot Ulcers.

NCT07209475

Status	RECRUITING
Phase	Phase 4
Sponsor	Royal Biologics
Enrollment	248 participants

Key Eligibility Criteria

Inclusion (14)

- Potential subjects are required to meet all the following criteria for enrollment into the study and subsequent randomization.
 - The potential subject is 18 years of age or older. At least 50% of the enrolled population must be ≥ 65 years of age.
 - The potential subject has a history of Type I or Type II Diabetes Mellitus requiring treatment by a physician with either oral medications and/or insulin replacement therapy.
 - Potential subjects have an ulcer characterized by the following:
 - Presence of a diabetic foot ulcer Wagner 1 or 2 grade at the first screening visit on any aspect of the foot, provided it is at or below the aspect of the medial malleolus. \[NOTE: If two or more DFUs are present with the same grade, the index ulcer is the largest ulcer and the only one evaluated in the study. Index ulcer must be more than 5 cm distant apart.\]
- ... and 9 more (see full listing online)

Exclusion (18)

- The Subject has a known life expectancy of < 1 year.
 - Index ulcer has been present for > 1 year.
 - Patient does not have adequate 2-week historical data demonstrating $< 20\%$ area reduction.
 - Subject is unable to comply with offloading device.
 - Presence of any condition(s) which seriously compromises the subject's ability to complete this study or has a known history of poor adherence to medical treatment.
- ... and 13 more (see full listing online)

Locations (8 total)

Lion Heart Clinical Research, Burbank, California, United States
Royal Research South, Miami, Florida, United States
Denali Health Atlanta, LLC, Stone Mountain, Georgia, United States
... and 5 more locations