A Study to Evaluate ENERGI-F703 GEL in Diabetic Foot Ulcer

NCT05930210

Status	RECRUITING
Phase	Phase 3
Sponsor	Energenesis Biomedical Co., Ltd.
Enrollment	230 participants

Key Eligibility Criteria

Inclusion (12)

- Subject must be at least 18 years old.
- Subject must have diagnosed with diabetes mellitus (DM), eg, currently under DM medication treatment or subjects with naïve DM with duplicated hemoglobin A1c over 6.5% and fasting plasma glucose over 126 mg/dL measured at least 1 week apart before screening.
- Subject must have at least 1 cutaneous ulcer on the foot and not healing for at least 4 weeks. The largest diabetic foot ulcer will be selected as target ulcer. If 2 or more ulcers have the largest size, the one with worst grade will be selected. If 2 or more ulcers have the largest size and grade, the one with longest duration will be selected.
- The target ulcer is classified as Grade 1 to Grade 2 ulcer according to Wagner Grading System and with ulcer size of 1.5 cm2 to 25 cm2.
- Diabetic foot ulcers should be free of any necrosis or infection

... and 7 more (see full listing online)

Exclusion (13)

- History or evidence of osteomyelitis as confirmed by the investigator. An x-ray/pathology assessment of debridement or a probe-to-bone (PTB) test will be used to determine presence of osteomyelitis. However, participants who have a history or evidence of osteomyelitis in other parts of their body are eligible to participate in the study. If the medical history of osteomyelitis was cured by antibiotic therapy, surgery or amputation for more than 1 year, and no recurrence, no finding to the current leg and foot after testing, the participant can be enrolled
- With target ulcer size decreased by at least 30% after at least 2 weeks of standard of care-only period between screening and randomization
- Subjects with highly exudated wounds which require dressing changes more than 3 times a day may be enrolled, but heavily exudated wounds should not be selected as target ulcers
- With poor nutritional status (serum albumin \<2g/dL or prealbumin \<10 mg/dL), poor diabetic control (hemoglobin A1c \>12%), a leukocyte counts \<2,000/mm3, abnormal liver function (aspartate aminotransferase, alanine aminotransferase \>3 x upper limit of normal range) within 21 days before Randomization visit
- Requiring treatment with systemic corticosteroids, immunosuppressive or chemotherapeutic agents

... and 8 more (see full listing online)

Locations (24 total)

A and D Doctor Center, Miami, Florida, United States
Bioclinical Research, Miami, Florida, United States
Reliant Medical Research, Miami, Florida, United States
... and 21 more locations