

Prospective Case Series Evaluating the Efficacy and Safety of NeoThelium FT for Diabetic Foot Ulcers

NCT07039396

Status	RECRUITING
Phase	Not Applicable
Sponsor	NuScience Medical Biologics, LLC
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (10)

- Male or Female, 18 years of age or older
 - Subject has a medical diagnosis of Type I or Type II Diabetes Mellitus requiring oral or glycemic control and/or insulin replacement therapy with a diabetic foot ulcer
 - Subject has a diabetic foot ulcer of Wagner grade 1, 2, or 3 without infection or clinically visible exposed bone. Wagner 3 is acceptable if the diagnosis is acute osteomyelitis and the subject has successfully completed IV antibiotic treatment prior to screening.
 - Ulcer area is a minimum of 0.5 cm² and a maximum of 25 cm² at first treatment visit
 - Subject is able and willing to follow the protocol requirements
- ... and 5 more (see full listing online)

Exclusion (14)

- Subject is unable to comply with protocol treatment
 - Target ulcer is a Wagner 3 of acute osteomyelitis that has not been successfully treated with 6 weeks of IV antibiotics or is diagnosed as chronic refractory osteomyelitis.
 - Wagner 3, 4, or 5 involving tendon, bone, or joint.
 - Presence of systemic infection, sepsis, or osteomyelitis at screening.
 - Multiple DFUs on the same foot with \leq 2 cm separation from the target ulcer.
- ... and 9 more (see full listing online)

Locations (3 total)

MedCentris of Alexandria, Alexandria, Louisiana, United States
MedCentris of Leesville, Leesville, Louisiana, United States
MedCentris of Many, Many, Louisiana, United States