

# Prospective Case Series Evaluating the Efficacy and Safety of NeoThelium FT for Venous Leg Ulcers

NCT07061613

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

## Key Eligibility Criteria

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### Inclusion (12)

- Male or Female, 18 years of age or older
- Subject has a medical diagnosis of venous leg ulcer or venous insufficiency with a lower extremity wound
- Subject has a venous leg ulcer without infection or clinically visible exposed bone
- Index wound is a minimum of 1 cm<sup>2</sup> and a maximum of 30 cm<sup>2</sup> at first treatment visit
- Adequate circulation if wound is location on the lower extremity demonstrated by an ABI of  $\geq 0.7$  and  $\leq 1.3$ , or TBI of  $\geq 0.6$  within 30 days prior to informed consent OR an arterial ultrasound noted with patent circulation and without significant stenosis 90 days prior to the first treatment visit.

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

### Exclusion (12)

- Subject is unable to comply with protocol treatment
- Presence of infection prior to screening.
- Multiple VLUs on the same leg with  $\leq 2$  cm separation from the target ulcer.
- Subject has comorbid conditions that may compromise subject safety or wound healing in the opinion of the investigator, such as serious cardiovascular, renal, liver, pulmonary, autoimmune, palliative care, or inherited blood disorders
- Subject actively being treated for malignant disease or history of malignancy or radiation therapy at the site of wound.

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

## Locations (2 total)

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MedCentris of Metairie, Metairie, Louisiana, United States  
MedCentris of Slidell, Slidell, Louisiana, United States