

# Non-healing Venous Leg Ulcers Treated With Standard Care With or Without BR-AC

NCT06811909

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Status	RECRUITING
Phase	Not Applicable
Sponsor	BioStem Technologies
Enrollment	60 participants

## Key Eligibility Criteria

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### Inclusion (14)

- Patient has signed the informed consent form.
- Male or female patient at least 18 years of age or older, as of the date of the screening visit.
- Has a VLU between the knee and ankle (at or above the malleoli), with a surface area in the range of e 2.0 cm<sup>2</sup> and d 20.0 cm<sup>2</sup> when measured by the investigator staff at the screening visit using the eKare device post debridement.
- If the subject presents with  $\geq 1$ , but  $\leq 3$  VLU on the same leg, the largest ulcer will be selected as the target ulcer.
- If the target ulcer is  $\leq 1$ cm from another VLU, the ulcers should be traced as a single target ulcer provided at least one of the ulcers is at least 2.0 cm<sup>2</sup> in area and the total surface area of the VLUs is  $\leq 20.0$  cm<sup>2</sup>.

... and 9 more (see full listing online)

### Exclusion (19)

- A target ulcer of non-venous etiologies (e.g., sickle cell anemia, necrobiosis lipoidica diabetorum, pyoderma gangrenosum, vasculopathic or vasculitic).
- Acute Deep Vein Thrombosis (DVT), defined as the first 10 days from onset of symptoms, or any DVT for which compression is considered by the Investigator to be contraindicated.
- Clinical evidence of ulcer bed infection, or infected hardware.
- Documented history of osteomyelitis at the target ulcer location within six (6) months preceding the screening visit.
- Refusal or inability to tolerate compression therapy.

... and 14 more (see full listing online)

## Locations (23 total)

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Site 17, Guntersville, Alabama, United States  
Site 2b, Castro Valley, California, United States  
Site 19b, Glendale, California, United States

... and 20 more locations

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<https://clinicaltrials.gov/study/NCT06811909>

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