A Study to Evaluate the Safety and Effectiveness Transdermal Compress Device in Participants With Transfemoral Amputations

NCT06134167

Status	RECRUITING
Phase	Phase 3
Sponsor	Balmoral Medical company
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (8)

- Participant must be able to understand the investigational nature of this study and has reviewed and provided written, informed consent prior to any study-specific procedures.
- Participant is a skeletally mature male or female and is 18 - 60 years of age at screening. Participants \< 22 years of age require radiographic confirmation of skeletal maturity and must have failed the use of conventional prosthesis.
- Participant has an estimated BMI of e 18.5 and d 40 kg/m2 and weight d 245 lbs without prosthesis.
- Participant has unilateral or bilateral transfemoral limb loss without bone or vascular disease.
- Participant has problems with conventional prostheses or is not able to use a prosthesis at all or is anticipated to experience problems with a socket prosthesis in the investigator's judgment.

... and 3 more (see full listing online)

Exclusion (16)

- Female participants who are pregnant, nursing, or have a planned pregnancy during the first 12 months post-surgical implantation.
- Participant had a prior osseointegrated device implanted in the lower limb planned for the study device.
- Participant has a history of systemic or localized infection at the residual limb site within 6 months prior to Study Day 1.
- Participant has any distant foci of infections.
- Participant has a history of sepsis within 6 months prior to Study Day 1.

... and 11 more (see full listing online)

Locations (9 total)

UC Davis Medical Center, Sacramento, California, United States
University of Colorado Anschutz Medical Campus, Aurora, Colorado, United States
Northwestern Memorial Hospital, Chicago, Illinois, United States
... and 6 more locations