Regenerative Peripheral Nerve Interface for Control of Lower Limb Prostheses

NCT06275282

Status	RECRUITING
Phase	Not Applicable
Sponsor	University of Michigan
Enrollment	3 participants

Key Eligibility Criteria

Inclusion (5)

- Unilateral amputation of the leg proximal to the knee at least 6 months prior to enrollment.
- Low surgical risk (American Society of Anesthesiologists Class I and II).
- For participants without existing RPNI grafts (at the time of enrollment), the residual limb must have sufficient soft tissue quality to support performance of the RPNI operative procedures. Participants sustaining severe crushing or avulsion injuries with substantial superficial and deep scarring may not be appropriate candidates for inclusion in the study.
- Amputee Mobility Predictor with prosthesis (AMPPRO) score of at least 37 (Gailey et al. 2002).
- Sufficient clearance to a motorized prosthetic leg without the necessity for shoe lifts or extenders on the contralateral limb.

Exclusion (12)

- Severe pain syndrome including complex regional pain syndrome or severe phantom pain. All of these conditions would suggest pathological activity of the nerve and would exclude the participant from participation.
- Untreated mental health disorders and if they have any DSM-5 diagnoses, they must receive approval to participate from their mental health professional.
- Any medical conditions that, in the opinion of the Principal Investigator, would place them at high risk for a surgical procedure including recent myocardial infarction, cerebrovascular accidents, deep venous thrombosis, pulmonary embolus, uncontrolled diabetes, or end stage renal disease.
- Participants must not have used tobacco for at least one month prior to enrollment in the study.
- Participants must agree to not use tobacco for the duration of the study.

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

Locations (1 total)

University of Michigan, Ann Arbor, Michigan, United States