

Multi-functional Neuroprosthetic System for Restoration of Motor Function in Spinal Cord Injury

NCT02329652

Status	RECRUITING
Phase	Not Applicable
Sponsor	Anne Bryden
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (6)

- Diagnosis of cervical level spinal cord injury, either complete or incomplete; International Standards for Neurological Classification of Spinal Cord Injury (INSCSCI) motor level of C4 through C8; American Spinal Injury Impairment Scale (AIS) grade A, B, C, or D; six months or more post-injury
 - Biceps/brachialis/brachioradialis strength of 2/5 or higher on Manual Muscle Test
 - Peripheral nerve innervation to upper extremity and trunk muscles, including a grade 3/5 or higher stimulated strength (Manual Muscle Test) in at least two of the following muscles in one arm: adductor pollicis, abductor pollicis brevis, flexor pollicis longus, extensor pollicis longus, extensor digitorum communis, flexor digitorum superficialis, flexor digitorum profundus, pronator quadratus, extensor carpi ulnaris, extensor carpi radialis brevis, extensor radialis longus, flexor carpi ulnaris, flexor carpi radialis, first dorsal interosseous; and in at least two of the following muscles: left/right gluteus maximus, left/right erector spinae, left/right quadratus lumborum,
 - Age \geq 16 years
 - Medically stable - cleared for surgery
- ... and 1 more (see full listing online)

Exclusion (14)

- Currently pregnant (neuroprosthesis implantation delayed until no longer pregnant)
 - Other neurological conditions (multiple sclerosis, diabetes with peripheral nerve involvement)
 - History of coagulopathy, HIV, severe cardiopulmonary disease, severe bradycardia, severe autonomic dysreflexia, or chronic obstructive pulmonary disease.
 - Active untreated infection such as decubitus ulcer, urinary tract infection, pneumonia
 - Presence of other active implantable medical devices with unknown or untested interaction with the NNP implant
- ... and 9 more (see full listing online)

Locations (1 total)

MetroHealth Medical Center, Cleveland, Ohio, United States

<https://clinicaltrials.gov/study/NCT02329652>

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