

Robotic Assisted Upper-Limb Neurorehabilitation in Stroke Patients

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- Funding Agencies: VA Cooperative Studies Program and RR&D

Description:

CSP #558 is a randomized, multi-center, outpatient phase II trial to assess the safety and efficacy of robot-assisted therapy for neurorehabilitation in chronic stroke patients with moderate to severe upper extremity impairment. The primary hypothesis of this study is that robotic training compared with usual care and intensive conventional treatment will lead to improved upper extremity function. Objectives: The primary objective of CSP #558 is to test the efficacy of robotic training in a phase II trial. The primary hypothesis of this study is that compared with usual care and intensive conventional treatment, robotic training will lead to improved upper extremity function as measured by the Fugl-Meyer scale, motor domain, at 12 weeks. The second primary objective will be the safety assessment of the four-module robot. The secondary hypotheses are that compared with usual care and intensive conventional treatment, robotic training will lead to improved quality of life and task performance involving proximal and distal control of the paretic arm. If the robotic training is effective, two other secondary objectives are to evaluate its early (less than 12 week) and late (36 week) effects on the primary and secondary outcomes. The tertiary objective is to use the MIT-MANUS system as a quantitative assessment instrument to collect the kinematic and kinetic submovement changes for point-to-point movements according to each randomized group. The primary purpose of this information is to aid in helping to better understand the neuroscience of motor recovery during rehabilitation and during natural history.

Research Plan & Methodology:

Briefly, all eligible patients who give written informed consent will be randomized to one of three treatment arms: 1) usual care; 2) intensive conventional therapy; or 3) robotic training. The randomization will be stratified by medical center and stroke severity (moderate vs. severe) using adaptive randomization because of the small number of participants expected to be enrolled at each site. The planned accrual period is 24 months; all participants will be followed for nine months with scheduled clinic visits at 6, 12, 24 and 36 weeks. Participants assigned to intensive conventional therapy or robot-assisted therapy will receive treatment for 12 weeks consisting of three one-hour sessions a week for 36 sessions and then usual care for the remainder of follow-up. Participants assigned to usual care will receive the usual chronic stroke care as delivered at each participating medical center (typically consisting of medications and recommendations for secondary stroke prevention, routine follow-up clinic visits, and emergent care visits as needed) for 36 weeks. At the end of completion of follow-up (36 weeks), participants assigned to usual care will be offered, as compassionate care, their choice of either robot-assisted or intensive conventional therapy delivered according to the same protocol as above (1 hour sessions, 3 times a week for 12 weeks).

Milestones:

October 2006 – First subject enrolled.

February 2007 – Interim analysis; usual care group dropped as part of planned adaptive design

Future Grant and Publication Plans:

Analysis planned for 2009-2010, grant and publication to follow.

Clinical Relevance:

Stroke is the leading cause of disability for older Americans, including veterans. Much of this disability can be traced to the lasting neurological impairments in stroke survivors, particularly when the functional deficits affect the arm and hand. The prevalence of stroke-induced chronic neurological impairment for veterans approaches 100,000 and affects over five million people with stroke in the general US population. Currently, there are no definite rehabilitative therapies for chronic stroke patients. Accordingly, there is a strong clinical impetus to develop interventions to restore neurological function, including during the chronic period of stroke recovery. Innovations in clinical robotic technology in conjunction with advances in the understanding of potential significant neurological recovery in the chronic stages of stroke now make it possible to test a promising new therapy using task-specific, robot-assisted neurorehabilitation for the upper-limb in chronic stroke patients.