Neural plasticity in patients with brachial plexus avulsion after intercostal-musculocutaneous nerve transfer

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The primary objective of this study is to identify the brain changes following peripheral nerve injury and establishing their functional role in recovery. The secondary objective is to evaluate new fMRI methodology in a patient population.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Observational invasive

Summary

ID

NL-OMON31174

Source
ToetsingOnline

Brief title
Neural plasticity in BPA patients

Condition

- Spinal cord and nerve root disorders

Synonym
brachial plexus avulsion, nerve rupture

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Stichting Technische Wetenschappen (STW)

Intervention

Keyword: brachial plexus avulsion, functional MRI, neural plasticity

Outcome measures

Primary outcome

fMRI data acquired while subjects perform a motor or cued voluntary breathing

task

Secondary outcome

resting state fMRI data (where subjects lie in the scanner with eyes closed,

instructed to do nothing) to investigate functional connectivity in the brain,

and DTI data to investigate structural connectivity in the brain

Study description

Background summary

Contrary to the classical view of a pre-determined wiring pattern, there is considerable evidence that cortical function and representation of body parts are continuously modulated in response to activity and behavior but also as a result of peripheral injury such as amputation or a brain injury such as stroke. These changes in plasticity may account for recovery of function. Both functional and structural changes are thought to play a role in this process. It is debated though, to what extent these changes cause recovery of function, or whether they might even inhibit recovery.
In this study, we want to investigate the plastic changes in the central nervous system underlying recovery of biceps function in patients with a root avulsion of the brachial plexus leading to paralysis of an upper limb. In some cases, transfer of intercostal nerves (ICN) to the musculocutaneous motor branch can yield a favorable outcome. After transfer, central ICN motor programs for respiration and posture control become connected to the biceps muscle. Initially, biceps contraction can only be effected by means of a voluntary respiratory effort. At the end stage of reinnervation, however, volitional control over biceps muscle contraction can be achieved without resorting to respiratory effort.

Study objective

The primary objective of this study is to identify the brain changes following peripheral nerve injury and establishing their functional role in recovery. The secondary objective is to evaluate new fMRI methodology in a patient population.

Study design

Three groups of subjects will be compared: a healthy control group, a patient group with good biceps function after ICN-MCN transfer and one with no functional recovery after this procedure. Different types of MRI data will be collected. fMRI data will be acquired with two different functional paradigms, one involving biceps contraction (real and imagined) and one involving cued voluntary breathing. Additionally, resting state fMRI and DTI data will be acquired to investigate functional and structural connectivity, respectively.

Study burden and risks

There are no known risks associated with participating in an fMRI study. This is a technique involving no catheterizations or introduction of exogenous tracers. Numerous children and adults have undergone magnetic resonance studies without apparent harmful consequences. Some people become claustrophobic while inside the magnet and in these cases the study will be terminated immediately at the subject's request. The only absolute contraindications to MRI studies are the presence of intracranial or intraocular metal, or a pacemaker. Relative contraindications include pregnancy and claustrophobia. Subjects who may be pregnant, who may have metallic foreign bodies in the eyes or head, or who have cardiac pacemakers will be excluded because of potential contraindications of MRI in such subjects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

age between 18 and 55
preferably male
preferably right handed

Exclusion criteria

metal in body, neurological impairments

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2008
Enrollment:	48
Type:	Actual

Ethics review

Approved WMO
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL18169.058.07