Reorganisation of the Motor Cortex After Transhumeral Arm Amputation.

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The aim of the study is to assess the cortical reorganisation after arm amputation using functional connectivity between and within the left and right motor hand areas using resting-state fMRI, and structural connectity using diffusion tensor...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44148

Source
ToetsingOnline

Brief title
Reorganisation of the motor cortex after arm amputation.

Condition

- Other condition

Synonym
Not applicable.

Health condition

Fundamenteel neurowetenschappelijk

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: European Research Council (ERC)

Intervention

Keyword: arm amputation, functional MRI, motor cortex

Outcome measures

Primary outcome

Functional connectivity (both within and between the left and right motor hand area in amputees and controls) obtained by resting-state fMRI will serve as a measure for cortical reorganisation. The results will be compared between the amputation and control groups.

Secondary outcome

Not applicable.

Study description

Background summary

After arm amputation, the brain is able to reorganise, such that the former hand area is *taken over* by neighbouring brain regions. However, there is also evidence that the former hand area is still active while performing attempted movements, and in a previous study we showed that it is possible to decode (that is, classify) the activity patterns of six different hand gestures made with the missing hand. However, as classification using machine learning techniques act as a black box, we would like to get insight in the processes of cortical reorganisation after arm amputation.

Study objective

The aim of the study is to assess the cortical reorganisation after arm amputation using functional connectivity between and within the left and right motor hand areas using resting-state fMRI, and structural connectity using

diffusion tensor imaging (DTI).

Study design

This study is an observational study using functional MRI in a group of volunteers, consisting of subjects with and without arm amputation. We will record so-called resting-state fMRI to quantify the functional connectivity within and between the left and right motor hand area, and diffusion tensor imaging (DTI) to assess structural connectivity of the hand area with its surroundings. The results will be compared between the amputation and control groups.

Study burden and risks

There are no known risks associated with MRI acquisition. The technique does not require administration of any contrast agent or ionizing radiation. The Utrecht group has ample experience with MRI scanning (300 sessions per year on the 7 tesla MRI scanner). The MRI procedure is painless. Slight discomfort may occur due to peripheral nerve stimulation during scanning, or due to lying still with the head and part of the body confined in a tunnel-like device.

The results of this study are important for the brain-computer interface research in the UMC Utrecht. Individual subjects in this study are not expected to have any benefits from the outcome of this study.

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 18+
Right-handed
(according to Edinburg Handedness Inventory; amputees have to fill in the situation before amputation)
For experimental group: amputated right arm (above elbow), longer than 1 year before the study

Exclusion criteria

Damage to the brain
Noncompliance with MRI safety check list (claustrophobia, metal in the body, etc.)

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:	Recruitment stopped
Start date (anticipated):	05-04-2016
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	22-03-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL55291.041.15