Investigating neural plasticity and nuclear hyperexcitability in patients with oral-ocular facial synkinesis using 7 Tesla functional MRI

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To study the neuroplasticity of the brain due to facial synkinesis by assessing the somatotopy of the face on several cortexes of interest (primary and secondary somatosensory cortexes, the primary motor cortex, the supplementary motor cortex, the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Peripheral neuropathies
Study type	Observational non invasive

Summary

ID

NL-OMON51921

Source
ToetsingOnline

Brief title
fMRI study facial synkinesis

Condition

- Peripheral neuropathies

Synonym
Bell's Palsy; Facial paralysis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Facial synkinesis, functional MRI (fMRI), Neural plasticity, Nuclear hyperexcitability

Outcome measures

Primary outcome

The main study parameter is the hemodynamic response after stimulation of specific parts of the face. Within the areas of interest (primary motor cortex, the ventral lateral premotor cortex, the supplementary motor cortex, the primary somatosensory cortex (S1), the secondary somatosensory cortex (S2), the facial nucleus (pons), and the trigeminal nucleus (pons)), the temporo-spatial brain activity patterns after the different motor and sensory tasks are assessed, and the representation of the face is mapped on the cortexes of interest.

Secondary outcome

not applicable

Study description

Background summary

Facial synkinesis is one of the most common consequences after facial paralysis, defined as the inability to move muscles due to nerve damage. Facial synkinesis arises during recovery of nerve injury and is characterized by involuntary and synchronous contractions of muscles during facial movements. Patients* quality of life is major influenced by the disease. As patients experience problems with facial movements, this leads to difficulties in expressing emotions, eating, and drinking.
A common type of facial synkinesis is oral-ocular synkinesis, defined as eye closure during movement with the mouth. During movements of the mouth, the buccinator muscle plays an essential role. Both the trigeminal and the facial

nerve innervate the buccinator muscle, resulting in a complex sensorimotor feedback system between the nerves. Dysregulation of this feedback system is assumed to result in hyperexcitability of the trigeminal and facial nuclei in the pons. In addition, this will lead to cortical plasticity of the sensory and motor areas of the brain. Based on this, we hypothesize dysregulation of the sensorimotor feedback system in patients with facial synkinesis, resulting in differences in the neuroplastic organization of the primary and secondary somatosensory cortexes, the primary motor cortex, the supplementary motor cortex, and the ventral lateral premotor cortex compared to healthy control participants. In addition, we expect hyperexcitability of the trigeminal and facial nuclei. Therefore, this study aims to obtain a more detailed understanding of the neural reorganization of the sensory and motor areas as a consequence of facial synkinesis using 7T fMRI.

Study objective

To study the neuroplasticity of the brain due to facial synkinesis by assessing the somatotopy of the face on several cortexes of interest (primary and secondary somatosensory cortexes, the primary motor cortex, the supplementary motor cortex, the ventral lateral premotor cortex, the facial nucleus (pons) and the trigeminal nucleus (pons)) compared to healthy control participants.

Study design

A single center imaging study carried out in MUMC+. Every subject will undergo a single functional MRI scan in the 7 Tesla MRI scan of Scannexus. A scanning session takes approximately 1.5 hours. During the scan, participants are asked to perform motor and sensory tasks.

Study burden and risks

All subjects with facial synkinesis will be informed of the study by their treating physicians at the outpatient clinic of plastic surgery. If they express interest in the study they will be approached by the study group. The potential participants will be informed about the study and the procedures, and the subject information and consent form are handed out. If patients are willing to participate, an appointment is made with the researcher to sign the consent form.

On a later moment every subject will undergo a single functional MRI scan taking 1.5 hours. There are no follow-up moments. Subjects do not have any direct benefits in participating in the study. In the rare case an anomaly is identified on any of the fMRI images, this will be discussed with the subject and this information is shared with the general practitioner. The burden associated with participation in this study, involves the usual MRI side

effects (e.g. anxious or claustrophobic feelings). No radiation is involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

(1) absence of facial nerve transposition; (2) participants must be 18 years of age or older; (3) signed informed consent.

For patients who suffer from oral-ocular synkinesis, two extra criteria will be maintained: patients must have severe facial synkinesis based on the Sunnybrook facial grading system at the time the MRI scan is performed, and synkinesis must occur only on one side of the face.

Exclusion criteria

The following exclusion criteria will be maintained for both the patients with facial synkinesis as the control participants: previous neurosurgery and contraindications for MRI investigation, such as a pacemaker, implanted pumps or stimulators, iron materials (e.g., piercings), facial tattoos and permanent make up, or claustrophobia.

For control participants, one extra criteria will be maintained: the participant must have no forms of facial paralysis prior to the MRI examination and at the time of the MRI procedure.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-04-2022
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO

Date:	26-01-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

	Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-11-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL78991.068.21