Cortical inhibition and cortical plasticity in individuals with Neurofibromatosis type 1 using transcranial magnetic stimulation

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The primary objectives is to determine the difference in cortical inhibition and cortical plasticity between NF1 patients and unaffected controls.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Neurological disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON45482

Source
ToetsingOnline

Brief title
Inhibition and plasticity in NF1

Condition

- Neurological disorders congenital
- Cognitive and attention disorders and disturbances

Synonym
Neurofibromatosis type 1, Von Recklinghausen disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: Inhibition, NF1, Plasticity, TMS

Outcome measures

Primary outcome

- Cortical inhibition as reflected by SICI using a conditioning pulse with 60%RMT intensity

- Cortical plasticity as reflected by iTBS induced increase of MEP*s over the time course of 20 minutes after plasticity induction.

Secondary outcome

- To determine the difference in motor skill learning between NF1 patients and unaffected controls.

- To determine the correlation between cortical inhibition and motor skill learning

- To determine the correlation between cortical plasticity and motor skill learning

- To determine the correlation between cortical inhibition and cortical plasticity

- To determine whether there is a difference in cortical inhibition as measured by the SICI (80%) TMS paradigm between adults with NF1 and unaffected controls

- To determine whether there is a difference in cortical inhibition measured by the CSP TMS paradigm between adults with NF1 and unaffected controls.

Study description

Background summary

Many individuals with Neurofibromatosis type 1 (NF1) suffer from cognitive and behavioural disabilities. The underlying cause of these disabilities has been extensively studied in Nf1 mouse models. This revealed that, at a neuronal level, cognitive disabilities seem to be caused by an increased firing of inhibitory interneurons and, therefore, an decreased synaptic plasticity. To further study the role of cortical inhibition and plasticity in the cognitive and behavioural deficits in NF1 patients we need a non-invasive method to study these neurophysiological processes.

Study objective

The primary objectives is to determine the difference in cortical inhibition and cortical plasticity between NF1 patients and unaffected controls.

Study design

Observational case-control study

Study burden and risks

The participants will visit the Erasmus MC once. Neuropsychological tests and non-invasive neurophysiology measurements are assessed during this visit. Total time investment by the participants for visits and testing will be ± 6 hours. Previous studies concluded that TBS appears to be safe, however it should be applied with caution (Hong et al., 2015; Oberman et al., 2011). We will make use of a screening checklist for risk factors in order to avoid potential TMS-related side effects. The participants will be reimbursed for travel costs and they will receive 100,- euros. This study is aimed at studying a NF1 specific neuronal dysfunction. Thus, testing only healthy volunteers cannot produce data that will give more insight into the functioning of the brain of NF1 patients.

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 - 55 years at inclusion
- Oral and written informed consent
- Right-handed
- NF1 patients with a clinically confirmed diagnosis

Exclusion criteria

- Pregnancy
- Not passing the Rossi safety check-list for undergoing a TMS-measurement (Rossi et al., 2009)
- Segmental NF1
- Psychoactive agents

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2018
Enrollment:	62
Type:	Actual

Ethics review

Approved WMO

Date:	14-06-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL59730.078.17