Cortical plasticity of Visual Evoked Potentials in Neurofibromatosis Type 1 patients

Published: 27-04-2020
Last updated: 10-04-2024

To investigate plasticity in the visual cortex in NF1 patients, we will compare the VEPs evoked by checkerboard reversals at baseline and after a modulation block at T1, T2 and T3 of NF1 patients with those of controls.

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

Summary

ID

NL-OMON49267

Source
ToetsingOnline

Brief title
VEPs 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: Neurofibromatosis type 1, Plasticity, Visual Evoked Potentials

Outcome measures

Primary outcome

Plasticity as measured by the change in VEP peak amplitudes at T1, T2 and T3 after a modulation block of 10 minutes checkerboard reversals compared to the baseline measurements.

Secondary outcome

- VEPs parameters, such as latency and peak amplitudes of P100, at baseline measurements of patients and controls.

- Parameters of visual information processing, such as reaction time, accuracy and speed of the eye movements, using a remote eye tracker

- Relationships between cortical plasticity as measured by an increase in VEP peak amplitudes over time, and the parameters of visual information processing.

Study description

Background summary

NF1 is an autosomal dominant genetic disorder and is characterized by a wide variability in clinical manifestations. Many patients with Neurofibromatosis type 1 (NF1) suffer from cognitive deficits that can affect their quality of life. Based on studies in NF1 mice, it is hypothesized that the underlying cause of these cognitive disabilities results from increased neuronal inhibition that affects synaptic plasticity. Synaptic plasticity is essential for learning and memory. Whether changes in neuronal plasticity are also underlying the cognitive deficits in NF1 patients is unknown. Recently, cortical plasticity in humans has been investigated using Electroencephalography (EEG) by studying Visual Evoked Potentials (VEPs) in response to visual stimulation measured from the visual cortex. To investigate the role of cortical plasticity in the cognitive deficits in adults with NF1,

we will measure VEPs in NF1 patients and controls.

Study objective

To investigate plasticity in the visual cortex in NF1 patients, we will compare the VEPs evoked by checkerboard reversals at baseline and after a modulation block at T1, T2 and T3 of NF1 patients with those of controls.

Study design

Observational case-control study

Study burden and risks

The total time investment for participants will be ±3 hours. The burden of the VEP recording and the visual presentation of checkerboard reversals is considered to be low, with no side effects. The eye-tracking procedure also has no side-effects and is not experienced as unpleasant. Participants will be reimbursed with ¤75 and compensated for travel and parking expenses. There are no benefits from this study for the participants, except for the reimbursement. Since this study is aimed at studying an NF1 specific neuronal dysfunction, solely testing healthy volunteers cannot give us further insights.
Additionally, the study might contribute to reliable neurophysiological outcome measures in treatment intervention studies.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age; between 18-55 years at inclusion
- Being capable of providing written informed consent
- Ability to understand the Dutch language
- Healthy (no history of neurological or psychiatric disorders)
- NF1 patients with a genetically or clinically confirmed diagnosis

Exclusion criteria

- Use of psychoactive agents
- History of or current presence of neurological or psychiatric disorders (excluding a history of attention deficit disorder or autism for the NF1 patients)
- Other neurological illness influencing the functioning of the central nervous system or visual tract involved in the VEP recordings.
- Neurological illness of the peripheral nervous system involving the sensory or visual function of the eyes.
- Segmental NF1
- Severe visual problems or blindness

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:	Recruitment stopped
Start date (anticipated):	17-06-2020
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	27-04-2020
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	NL72409.078.19