The value of nerve ultrasound in patients with neurofibromatosis type 1

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

Summary

ID

NL-OMON48220

Source
ToetsingOnline

Brief title
Nerve ultrasound in neurofibromatosis type 1

Condition

- Neurological disorders congenital
- Nervous system neoplasms benign
- Nervous system neoplasms benign

Synonym
neurofibromatosis type 1, Von Recklinghausen's 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: high-resolution ultrasound, nerve ultrasound, neurofibroma, neurofibromatosis type 1

Outcome measures

Primary outcome

The main study parameters are the number of HRUS abnormalities and their

characteristics (cross-sectional area, presence of vascularization) and the

presence or absence of neurological deficits.

Secondary outcome

Secondary study parameters are:

- the number of newly detected nerve abnormalities with HRUS after two years of

follow-up;

- the increase in CSA and/or vascularization of nerve abnormalities detected

with HRUS after two years of follow-up.

Study description

Background summary

Individuals with neurofibromatosis type 1 (NF1) are prone to develop benign and malignant tumours of the central and peripheral nervous system. Plexiform neurofibromas arise from multiple nerve fascicles, can grow along the length of a nerve and can also extend into surrounding structures, causing pain and neurological deficits. The relation between morphologic changes of the nerve and pain or neurological deficits is not known. It is not yet possible to predict pain or neurological deficits based upon (early) morphological changes. In areas of an existing plexiform neurofibroma, there is a high risk of developing a malignant peripheral nerve sheath tumour, a tumour with a poor outcome. No quick and cost-effective technique exists so far for examining the peripheral nerves of NF1 patients and screening these patients for peripheral nerve tumours.

Study objective

This will be an explorative study to examine the value of high-resolution ultrasound (HRUS) of the peripheral nerves in NF1 patients. The primary objective of this study is to determine HRUS abnormalities in a large group of NF1 patients, and to explore the differences in HRUS abnormalities between patients with or without deficits. A secondary objective is to evaluate the stability and growth of plexiform neurofibromas and the incidence of newly detected nerve abnormalities during two years of follow-up.

Study design

Cross-sectional (observational) study and longitudinal study.

Study burden and risks

Participation in the study means patients will undergo a standardized neurological examination, nerve conduction studies (NCS) and high-resolution ultrasound (HRUS) twice: as soon as possible after inclusion and two years later. In the case of neurological deficits, electromyography will also be performed directly after NCS. For patients this will mean two extra visits to the outpatient clinic, in addition to the regular visits to their neurologist.
The neurological examination will be performed during regular visits. NCS and HRUS will be combined in one extra visit at inclusion and one after two years.
If patients want to be informed of the results they will be contacted by phone.
Clinical examination and HRUS are painless, NCS and electromyography might cause some physical discomfort. Only electromyography may cause mild adverse events (hematoma, haemorrhage, infection).

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 years
- Diagnosed with neurofibromatosis type 1
- Treatment at the outpatient clinic of the Erasmus MC Cancer Institute (Rotterdam)

Exclusion criteria

- comorbidity associated with (poly)neuropathy (e.g. alcoholism, diabetes mellitus)
- comorbidity mimicking neuropathic complaints (e.g. myelopathy)
- inability to give informed consent or to undergo HRUS

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	11-07-2019
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	08-04-2019
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	NL68748.078.19