Pilot study on 3D-Ultrasound of Peripheral Nerves

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

Summary

ID

NL-OMON47530

Source
ToetsingOnline

Brief title
3D-Ultrasound of Peripheral Nerves

Condition

- Peripheral neuropathies

Synonym
Nerve Disease, Polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis
Source(s) of monetary or material Support: Investigator initiated Onderzoek vanuit de Maatschap Neurologie Elisabeth-Tweesteden Ziekenhuis. 3D-echo apparatuur wordt beschikbaar gesteld door Toshiba Medical Systems Nederland (Zilverstraat 1;2718RP;Zoetermeer;Nederland),Toshiba Medical Systems Nederland

Intervention

Keyword: 3D Ultrasound, Nerve Ultrasound, Peripheral Nerves, Polyneuropathy

Outcome measures

Primary outcome

Several parameters will be evaluated in this study.

- CSA measurements obtained from the images acquired with 3D ultrasound.

- The quality of sonographic images of 3D ultrasound over a longer tract will be evaluated semi-quantitatively following earlier published criteria.

- 3D reconstruction images (and the possibility of creating them in the three groups of participants).

- Volumetric measurement values (and the possibility of obtaining them in the three groups of participants).

- Inter-observer variability: the CSA measurements and volumetric measurements obtained by 2 different investigators with 3D ultrasound will be compared. Also the CSA measurements obtained with 3D and 2D ultrasound by one investigator each will be compared.

Secondary outcome

NA

Study description

Background summary

High-resolution ultrasonography (HRUS) provides very useful information on nerve pathology and is of diagnostic and prognostic value in polyneuropathies. The most commonly assessed parameter in HRUS is measurement of the cross sectional area (CSA), which is measured at a single plane of the nerve at a

predetermined measurement site. However, there seems to be a fair degree of interobserver variability in CSA measurements and this may hinder performance and interpretation of HRUS especially when sonography is used for follow-up assessments of peripheral nerve pathology. Studies investigating MRI in peripheral neuropathy showed that tumor volumetry was more reliable as a follow-up tool than measuring CSA. In several fields of medicine 3D ultrasound is used to gain additional insight in pathology, but research into this technique when assessing peripheral nerves is very limited.

Study objective

In this pilot study we want to investigate if 3D ultrasound can adequately visualize long nerve tracts and if 3D reconstructions of nerves and volumetric measurements can be made with this technique. If this is the case, this could not only decrease inter-observer variability in HRUS, by allowing more easy recognition of the site of maximal enlargement for CSA measurement and by measuring (changes in) nerve volume over a longer tract, but it could also give additional insight in (spatial distribution of) nerve pathology, which could have diagnostic, prognostic and therapeutic value in case of peripheral nerve pathology.

Study design

This study is a cross-sectional pilot study, in which peripheral nerves of several groups of patients will be examined with 3D-Ultrasound. Half of the patients will undergo this investigation twice to determine inter-observer variability of the techniek. The other half will undergo a 3D-Ultrasound and a 2D-Ultrasound in order to compare the two techniques.

Study burden and risks

The risks associated to participating are negligible. There are no known harmful effects of ultrasonography or electrodiagnostic testing. 3D-ultrasound is a technique that is not commonly used in neurology up to this date, but it is already frequently applied in other fields of medicine, e.g. gynaecology. There is a small burden for patients, since they need to invest time. We believe this investment is justifiable to determine if 3D-Ultrasound of peripheral nerves is useful, since this technique can have multiple applications if that would be the case.

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

- A diagnosis of CIDP, MMN, MIDN according to the international guidelines
or
- A diagnosis of axonal polyneuropathy, based on findings on EMG
or
- A diagnosis of NF1 according to the international guidelines, or genetically confirmed diagnosis of NF1
or
- Healthy control: participants without any neuropathic complaints (e.g. sensory loss, loss of strength);and
- Age 18-80

Exclusion criteria

- Being physically unable to undergo sonography

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2018
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	27-06-2017
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-04-2018
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL61847.028.17