Improved diagnosis for patients with immune-mediated neuropathies

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Evaluate the added value of new MRI and US techniques for the diagnosis of neuromuscular disorders such as MMN and CIDP and the MMN-mimic fSMA.

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

Summary

ID

NL-OMON44505

Source
ToetsingOnline

Brief title
INTEND

Condition

- Demyelinating disorders

Synonym
neuromuscular disorders

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NutsOhra

Intervention

Keyword: Diffusion Tensor Imaging (DTI), Magnetic Resonance Imaging (MRI),

neuromuscular disorders, Ultrasound

Outcome measures

Primary outcome

Correlation between MRI, US, NCS, muscle strength, disability scale.

Secondary outcome

1. NCS outcome (EFNS/PNS guideline)

a. Temporal dispersion, Conduction velocity, conduction block

2. US

a. Cross sectional area

b. Vascularization

c. Echo intensity

3. MRI

a. Diameters

b. Scoring of hyperintensities and swelling

c. DTI parameters and architecture of affected nerves and muscles

4. Muscle strength * hand-held dynamometry and MRC scores

5. Overall Neuropathy Limitations Scale (ONLS)

6. INCAT sensory Scale (ISS)

Study description

Background summary

Diagnosis of acquired immune mediated diseases affecting peripheral nerves like Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) and Multifocal Motor Neuropathy (MMN) currently relies on extensive electrophysiological conduction studies (NCS) in addition to neurological examination. However, the proximal

parts of the nerves (brachial plexus and major part of upper leg and lumbosacral plexus) cannot be reliably studied, so that diagnosis may be missed and patient may not receive proper immunosuppressive or -modulatory treatment.
In patients presenting with monomelic/focal motor deficits, an important differential diagnosis is that between MMN and focal/monomelic Spinal Muscular Atrophy (fSMA). MMN in contrast to fSMA can be treated. However, the above-mentioned limitations of NCS at proximal sites may hinder the distinction between both disease entities.

MRI and ultrasound (US) are promising techniques to serve as important adjunct tools to establish diagnosis of immune mediated neuromuscular disorders, as they allow for visualization of the proximal parts of the nerves.
In the current diagnostic guidelines, increased signal intensity on T2-weighted MRI, associated with a diffuse nerve swelling of the brachial plexus already is one of the supportive diagnostic criteria for MMN. New MRI and US techniques may be of additional value.

In this explorative study we will compare the results of extensive NCS measurements, muscle strength assessment, sensory examination, assessment of clinical disability, MRI and US in MMN and CIDP patients. These results will be used to study the nerves of fSMA patients with an equal clinical presentation as MMN patients, with emphasis on the proximal nerve parts. Patients will be recruited from an existing database and if possible new patients will be added.

Future prospects: replace (part of) the extensive NCS by the imaging techniques which will be less time consuming, less painful, thus more patient friendly, and hopefully an important aid to the diagnosis.

Study objective

Evaluate the added value of new MRI and US techniques for the diagnosis of neuromuscular disorders such as MMN and CIDP and the MMN-mimic fSMA.

Study design

Observational, diagnostic, cross-sectional.

Study burden and risks

Patients with MMN, CIDP and patients with focal motor deficits, currently diagnosed as fSMA, will be included. In case no recent (n<6 months) NCS is available this will be performed. Patients will undergo MRI and US of either arms or legs and brachial or lumbosacral plexus. To assess disease severity muscle strength and clinical disability will be measured.
Participation in this study will in no way interfere with any treatment decision.

Risks for undergoing NCS, MRI and ultrasound are minimal, provided precautions have been made to exclude those who are not allowed to enter the MRI scanner. A routine AMC questionnaire will be used. Only individuals with recent traceable MRI feasible prostheses will be included.
There are no direct benefits for participants.

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

* Signs and symptoms consistent with Multifocal Motor Neuropathy, Chronic inflammatory demyelinating polyneuropathy or Focal/monomelic Spinal Muscular Atrophy;* Adult (*18 years)
* Fulfilling the EFNS/PNS criteria

Exclusion criteria

* Subject is unwilling or unable to participate in this study and to give informed consent.
* Legally incompetent adult
* Use of drugs which are known to cause motor neuropathy
* Other diseases known to cause neuropathy or to reduce mobility
* Diseases known to lead to severe handicap or death at short notice
* Subject has a prosthesis which is not verifiable MR-compatible by registration number.
* Contraindications to undergo a MRI scan (I.e. pregnancy, claustrophobia, metal corpora aliena or metal implants such as pacemakers).

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):	20-05-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	31-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL48090.018.14