Visualization of nerves and muscles in the forearm - In patients with multifocal motor neuropathy (MMN), amyotrophic lateral sclerosis (ALS), and healthy volunteers

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To investigate the potential value of magnetic resonance imaging (MRI) and diffusion tensor imaging (DTI) on a 3 Tesla and 7 Tesla MRI system and ultrasound (US) to visualize the peripheral nerves and muscles in the forearm to diagnose MMN and ALS...

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

Summary

ID

NL-OMON40757

Source
ToetsingOnline

Brief title
VISA study

Condition

- Peripheral neuropathies

Synonym
multifocal motor neuropathy and amyotrophic lateral sclerosis, peripheral neuropathy and muscular atrophy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: amyotrophic lateral sclerosis, multifocal motor neuropathy, peripheral nerves, Visualization

Outcome measures

Primary outcome

The main study parameters will be on the one hand qualitative in terms of anatomy based on the anatomical MRI images (T1 and T2 sequences and 3D DTI tractography) and ultrasound images, and on the other hand quantitative in terms of diffusion parameters including the fractional anisotropy, mean diffusivity, axial diffusivity and radial diffusivity and ultrasound measurements including the cross sectional nerve and fascicle area, nerve length and echogenicity. These results will be compared to the EMG. With EMG it is possible to obtain information regarding the nerve and muscle conduction. Potential differences in conduction will be compared to ultrasound and MRI parameters.

Secondary outcome

NA

Study description

Background summary

Multifocal motor neuropathy (MMN) and amyotrophic lateral sclerosis (ALS) are intriguing but rare disorders that can be clinical similar in presentation.

Both diseases are characterized by their progressive, multifocal, asymmetric distribution of the nerves without any sensory involvement. However, as ALS is a dramatic and fatal disease within several years, MMN has a more benign disease course. In a later stadium, due to progressive axonal loss motor nerves patients can be severely disabled. Motor deficit usually starts and remains prominent in the distal arms. It is of extreme importance to distinct MMN from ALS, but this can be very challenging. The hallmark of MMN is conduction block (CB) on nerve conduction studies (NCS). However, these are not always found. Earlier diagnosis will be beneficial as it permits the introduction of therapies in an earlier stage of the disease. In MMN this means that treatment with immunoglobulins (IVIg) can be started. Around 80% of the patients improve significantly over longer time with repeated IVIg infusions. For ALS there is no cure which completely stops the degeneration of the nerves. The disease is progressive; the mean duration of survival is three to five years. Riluzole can slightly reduce disease progression by several months. No other therapies are available.
More diagnostic tools are urgently needed to distinct these diseases and start treatment minimizing the time delay.

Study objective

To investigate the potential value of magnetic resonance imaging (MRI) and diffusion tensor imaging (DTI) on a 3 Tesla and 7 Tesla MRI system and ultrasound (US) to visualize the peripheral nerves and muscles in the forearm to diagnose MMN and ALS and test its value to determine the disease progression and to compare this with the gold standard electromyogram (EMG).

Study design

A prospective monocenter pilot study of 10 MMN patients, 10 ALS patients, and 10 healthy volunteers (time frame: 12 months)

Study burden and risks

Subjects will have a MRI scan during 2 scan sessions of each 25 minutes using a 3.0T and 7.0T MRI scanner (Philips Medical Systems, Best). There are no known risks associated with MRI, beside temporary dizziness and claustrophobia. No contrast is needed. The burden for the MRI scan is relatively low. The subjects will obtain an ultrasound investigation of 20 minutes. There are no risks associated with ultrasound. Furthermore, an EMG will be obtained. EMG can be associated with an excitatory feeling and sometimes transient pain is mentioned. EMG will not affect the nerves or muscles in any way. The investigation takes approximately 45 minutes. There are no risks associated with EMG. Previous to the EMG study the arm will be warmed up for about 30 minutes.
The results of this study may help to better diagnose both diseases and

distinct MMN from ALS in the future which can be beneficial for further therapy and treatment plans of these 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

Patients with MMN
* Slowly progressive or stepwise progressive limb weakness
* Asymmetrical limb weakness
* Number of affected limb regions < 7. Limb regions are defined as upper arm, lower arm, upper leg, or lower leg on both sides
* Decreased or absent tendon reflexes in affected limbs
* Signs and symptoms are more pronounced in upper limbs than in lower limbs
* Age at onset of disease: 20*65 years;Patients with ALS

Inclusion criteria are based on the guidelines for diagnosis explained by [18]
* Evidence of lower motor neuron degeneration by clinical, electrophysiological or neuropathological examination
* Evidence of upper motor neuron degeneration by clinical examination
* Progressive spread of symptoms or signs within a region or to other regions, as determined by history or examination
* Patient should be between 20-65 years;Healthy controls
* Volunteers are healthy
* Volunteers are 18 year or older
* Volunteers are capable and prepared to sign an informed consent form

Exclusion criteria

Patients with MMN
* The patients should have no objective sensory abnormalities except for vibration sense
* The patients should have no bulbar signs or symptoms
* The patients should have no upper motor neuron features
* The patients should have no other neuropathies (eg, diabetic, lead, porphyric or vasculitic neuropathy; chronic inflammatory demyelinating polyneuropathy; Lyme neuroborreliosis; postradiation neuropathy; hereditary neuropathy with liability to pressure palsies; Charcot-Marie-Tooth neuropathies; meningeal carcinomatosis)
* The patients should have no myopathy (eg, facioscapulohumeral muscular dystrophy, inclusion body myositis);Patients with ALS
* Patients should not have other disease processes that might explain the signs of lower/upper motor neuron degeneration
* The patients should have no other neuropathies (eg, diabetic, lead, porphyric or vasculitic neuropathy; chronic inflammatory demyelinating polyneuropathy; Lyme neuroborreliosis; postradiation neuropathy; hereditary neuropathy with liability to pressure palsies; Charcot-Marie-Tooth neuropathies; meningeal carcinomatosis)
* The patients should have no myopathy (eg, facioscapulohumeral muscular dystrophy, inclusion body myositis);Healthy controls
* Volunteers with contra-indications for MRI (like a pacemaker, claustrophobia).
* Volunteers with known MMN, ALS or other neuropathy related disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	16-06-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL49006.041.14