MRI for MMN and CIDP - Towards improved diagnostic accuracy and dissection of pathophysiology.

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1. To study reproducibility of a qualitative scale for abnormality of brachial plexus MRI.2. To study usefulness of quantification of nerve size using maximum intensity projection techniques (MIP) , and compare results with HRUS of the brachial...

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

Summary

ID

NL-OMON48985

Source
ToetsingOnline

Brief title
MIMIC

Condition

- Autoimmune disorders
- Peripheral neuropathies

Synonym
immuun-mediated/treatable polyneuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Prinses Beatrix Spierfonds

Intervention

Keyword: CIDP, diagnostics, MMN, MRI

Outcome measures

Primary outcome

The main study parameters for objective 1, are:

1. (Semi-)quantitative rating of MRI-imaging of brachial plexus.

2. Cross-sectional area (CSA) on HRUS imaging (CSA measurements of median nerves and brachial plexus).

These parameters will be used to select those with highest diagnostic yield as endpoint.

The main parameters for objective 2, are:

1. MRI-DTI values (radial, axial and mean diffusivity (RD, AD and MD), fractional anisotropy (FA)).

The will be used to determine the distribution of parameters and nerve size that may be useful in the future for patients with CIDP and MMN.

Secondary outcome

NA

Study description

Background summary

Chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy (MMN) are rare causes of lower motor neuron syndromes that respond to treatment. Extensive nerve conduction studies (NCS) to detect abnormalities that suggest demyelination or conduction block (CB) are often burdensome. The

required specific expertise is another drawback. Abnormal qualitative magnetic resonance imaging (MRI) of the brachial plexus is a supportive criterion for a diagnosis of MMN and CIDP. Its specificity is excellent but sensitivity is limited. Potential improvements for MRI-imaging include quantitative analysis and advanced MRI-sequences. MRI-DTI techniques also have potential to clarify the pathophysiology of inflammatory neuropathies.

Study objective

1. To study reproducibility of a qualitative scale for abnormality of brachial plexus MRI.
2. To study usefulness of quantification of nerve size using maximum intensity projection techniques (MIP) , and compare results with HRUS of the brachial plexus.
3. To study feasibility of an MRI-DTI protocol for nerve(root)s in upper arm and brachial plexus in healthy controls and patients with MMN, CIDP. These techniques may be new tools to gain insight in pathophysiology and/or treatment response

Study design

To study objective 1 and 2, a cross-sectional study will be used to define quantitative cut-off values of abnormal nerve size of the brachial plexus and to select parameters with the highest diagnostic yield. A cross-sectional design will also be used to study objective 3, whether MRI-DTI parameters (i.e. altered diffusivity in radial and axial dimensions) are specific for CIDP and MMN. To study objective 4 we use a longitudinal design to explore whether MRI-DTI could be used as a biomarker for treatment response.

Study burden and risks

For the purpose of this project, patients will only have to undergo MRI. It offers little burden additional to the routine diagnostic procedures. MRI is safe, non-invasive and well tolerated. To minimize the hospital visits, neuro-imaging sessions will be planned in combination with the routine diagnostic procedures.

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

1. Age 18- 80 years.
2. Patients: confirmed diagnosis of CIDP or MMN, as defined by relevant diagnostic consensus criteria.
3. Disease controls: established diagnosis of relevant clinical mimic to diagnosis CIDP and MMN (CMT, lower motor neuron syndromes and axonal neuropathies).
4. Healthy volunteers: no previous diagnosis, sign/symptoms consistent with neuropathy

Exclusion criteria

1. age <18 or >80 years,
2. physically unable to undergo MRI or HRUS of the peripheral nervous system

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-09-2018
Enrollment:	190
Type:	Actual

Ethics review

Approved WMO Date:	11-07-2018
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	08-08-2018
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	06-01-2020
Application type:	Amendment
Review commission:	METC NedMec

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	NL62866.041.17