A research in patients with progressive multiple sclerosis, primary as well as the secondary form. Two groups of patients in which one group of patients receives IVIG medication and the patients of the other group do not receive medication for their progressive multiple sclerosis. With questionnaires we measure if there is a difference in quality of life and fatigue in these two groups of patients.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27216

Source
NTR

Health condition

Multiple Sclerosis is the most common immuun mediated inflammatoire demyelinisating disease of the central nervous system. In this study we focus on the progressive form of MS, primary as well as the secondary form. In these forms patients experience a progressive and chronical decline. In time they get more and more handicapped by their disease. The treatment of progressive MS remains an enormous challenge. Research has shown sometimes a temporary, no or barely significant on stabilizing the progression of disease.

The effects of intravenous immunoglobulins on progressive MS remain unclear until now. At this moment IVIG is not a recommended treatment for SPMS and PPMS. It is only prescribed in specialised MS centers. Earlier research has been done on the effect of IVIG in progressive MS on EDSS score and MRI imaging. As a secondary measure they have investigated the effect on quality of life and fatigue and did not find a significant effect. In this study we want to focus on quality of life and fatigue as a primary outcome measurement because we are convinced more research on this specific outcome in IVIG and progressive MS is needed.

Sponsors and support

Primary sponsor: Self financed study.
Source(s) of monetary or material Support: Self financed study.

Intervention

Outcome measures

Primary outcome

Quality of life and fatigue measured with questionnaires.

Secondary outcome

EDSS score.

Study description

Background summary

The research is carried out at the academic MS centre in the Zuyderland Hospital, the Netherlands.
Two groups of patients with progressive multiple sclerosis, primary as well as the secondary form, will be created. The one group is treated with intravenous immunoglobulins for at least 12 months, the other group does not receive any medication for their MS. There will be no interventions. In this research the patients will once fill in one questionnaire on quality of life and one questionnaire on fatigue.

The research has been accorded as not-WMO research by the METC of the Zuyderland Hospital.

Study objective

Multiple Sclerosis is a complex disease with a multifactorial cause. Progression in MS arises and persists by complex inflammatory reactions leading to neurodegeneration and tissue disturbance. Progressive MS is characterised by a degenerative proces and chronical loss of axons in the tractus corticospinalis. Hypothetical it can bet hat in these areas with disturbances in the immune system intravenous immunoglobulins have a healing effect.

In our knowledge, there has never been performed a research with quality of life and fatigue as a primary outcome measure in research done on the place of intravenous immunoglobulins in progressive multiple sclerosis. In this study we want to highlight these aspects.

Study design

The study population will exist off 100 patients. 50 patients in group 1 and 50 patients in group 2. Two groups of patients in which one group of patients receives IVIG medication (¡Ý12 months) and the patients of the other group do not receive medication for their progressive multiple sclerosis.

By matching we want to get the groups as equal as possible. This way we hope we can get a better conclusion out of the research. If it is possible we want to match on gender, age, form of MS, EDSS score (group 1 at beginning of treatment and group 2 the same years in history).

Only at one moment de questionnaires will be filled in by the patients. One questionnaire on quality of life and one questionnaire on fatigue. We will analyse the scores and compare the scores between the two groups.

Intervention

There wil be no interventions in this study. At only one time there will be filled in questionnares by the patients. One questuionnaire is the Fatigue Impact Scale and the other questionnaire is de MSQOL-54. Both in validated dutch versions.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria group 1 with IVIG:

- Patients with SPMS or PPMS according to the MacDonald criteria

- Male and female

- IVIG treatment ¡Ý 12 months

Inclusion criteria group 2 without IVIG:

- Patients with SPMS or PPMS according to the MacDonald criteria

- Male and female

- No IVIG treatment

Exclusion criteria

Exclusion criteria group 1 with IVIG:

- Patients with RRMS or PRMS

- Therapie with other disease modifying drugs for MS

- Pregnancy or labour < 1 year ago

Exclusion criteria group 2 without IVIG:

- Patients with RRMS or PRMS

- Therapie with other disease modifying drugs for MS

- Pregnancy or labour < 1 year ago

- Use of IVIG in the last 2 years

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2016
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-11-2016
Application type:	First submission

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
NTR-new	NL5982
NTR-old	NTR6146
Other	METC of the Zuyderland Hospital : 16N180

Study results