

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.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27216

Bron

NTR

Aandoening

Multiple Sclerosis is the most common immuun mediated inflammatoire demyelinating 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.

Ondersteuning

Primaire sponsor: Self financed study.

Overige ondersteuning: Self financed study.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Quality of life and fatigue measured with questionnaires.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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 process and chronic loss of axons in the tractus corticospinalis. Hypothetically it can be that 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.

Onderzoeksopzet

The study population will consist of 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 (every 12 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 the 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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria group 1 with IVIG:

- Patients with SPMS or PPMS according to the MacDonald criteria
- Male and female
- IVIG treatment ≥ 12 months

Inclusion criteria group 2 without IVIG:

- Patients with SPMS or PPMS according to the MacDonald criteria
- Male and female
- No IVIG treatment

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	16-11-2016
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	15-11-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5982
NTR-old	NTR6146
Ander register	METC of the Zuyderland Hospital : 16N180

Resultaten