Fatigue in autosomal dominant spinocerebellar ataxia (ADCA) and idiopatic late onset cerebellar ataxia (ILOCA)

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON32846

Source
ToetsingOnline

Brief title
Fatigue in spinocerebellar ataxia

Condition

- Movement disorders (incl parkinsonism)

Synonym
ataxia, spinocerebellar ataxia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W,donatie van de ADCA-patientenvereniging

Intervention

Keyword: fatigue, self assessment scales, spinocerebellar ataxia

Outcome measures

Primary outcome

Primary study parameters are: difference in FSS-score in our study population compared to (published) FSS scores in healthy controls and furthermore the correlation of FSS score and disease duration, severity of ataxia (quantified with the SARA: scale for assessment and rating of ataxia) and depression (quantified in the Beck depression inventory). ,

Secondary outcome

Secondary study parameters are: independent correlates of fatigue, studying the association of frequency and severity of fatigue, measured by FSS, and quality of life, motor function, disorders of sleep and cognitive functioning, assessed by the SF-36, the Rotterdam handicap scale, the Pittsburg sleep quality index, the Epworth sleepiness scale(ESS) and the mini mental state examination (MMSE)

Study description

Background summary

Autosomal dominant spinocerebellar ataxia (ADCA) and idiopathic late onset cerebellar ataxie (ILOCA) are relatively rare neuroodegenerative disorders. Apart from neurological symptoms, patients indicate fatigue as a severe and disabling problem. Studies adressing fatigue in other neurodegenerative disorders like Parkinson's disease (PD)and en multiple sclerosis (MS) and also in neuromuscular disorders, indicate a high incidence of severe fatigue in these disorders compared to healthy controls. In both PD and MS, fatigue does

not correlate with severity of motor dysfunction, it is hypothesized that fatigue is an independent symptom of neurodegeneration. Associations of fatique with depression, cognitive decline and sleeping disorders have been studied but there are no unequivocal conclusions.
In a pilot study, we have assessed the fatigue severity scale (FSS) and the international ataxia rating scale (ICARS) in 20 patients with SCA. The mean FSS was 5,5. indicating severe fatigue and this score is significantly higher than in healthy controls. Presence of fatigue did not seem to correlate with severity of ataxia, measured by the ICARS, however, FSS scores tended to rise with duration of disease.

Study objective

The primary objective of this study is to analyze the frequency and severity of fatigue in patients with spinocerebellar ataxia and to test whether duration of the disease, depression and the severity of ataxia are related to the severity of fatigue in these patients. These relationships will be adjusted for age and sex. The secondary objective is to identify the association between the frequency and severity of fatigue on the one hand and motor dysfunction, cognitive dysfunction, sleeping disorders and also specific SCA diagnosis on the other hand.

Study design

observational cross-sectional study

Study burden and risks

All participants will be asked to fill in six self-assessment scales, that will take aproximately 45 minutes of their time. We will ask 94 patients to visit the clinic for additional neurological examination and assessment of the mini mental state examination. This will take another 45 minutes time, plus travelling time. There are no risks for patients in participating this study

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

diagnosis of autosomal dominant spinocerebellar ataxia (ADCA) or idiopatic late onset cerebellar ataxia (ILOCA), age of 18 years and beyond, able to interpretate self-assessment scales, signed informed consent

Exclusion criteria

ataxia of unknown origin or other diagnosis
age below 18 years
severe psychiatric or cognitive deterioration or other conditions that prevent patients from adequate interpretation of self assessment scales

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2009
Enrollment:	94
Type:	Actual

Ethics review

Approved WMO

Date:	15-01-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL25401.078.08