The validation of anxiety rating scales in Parkinson's disease

Published: 29-10-2008
Last updated: 06-05-2024

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

Summary

ID

NL-OMON32820

Source
ToetsingOnline

Brief title
Anxiety in Parkinson's disease

Condition

- Movement disorders (incl parkinsonism)
- Anxiety disorders and symptoms

Synonym
anxiety, parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Michael J Fox Foundation for Parkinson's Research,Micheal J Foxx Foundation for Parkinson's Research

Intervention

Keyword: anxiety, anxiety rating scales, Parkinson's disease, phenomenology, validation

Outcome measures

Primary outcome

The primary study parameters are the validity and reliability of the anxiety rating scales used resp; the Neuropsychiatric Invertory, anxiety section, the Hamilton Anxiety Rating Scale. the Clinical Global Impression Scale, the Beck Anxiety Inventory and the Hospital Anxiety and Depression Scale.

Secondary outcome

Secundary study parameters are:

- prevalence rates of van anxiety disorders

- atypical anxiety syndromes will be looked into by exploratory clusteranalysis of items on the various anxiety scales

- anxiety states limited to 'off'periods and/or dyskinesia will be described by looking at score patterns across the additional questions pertaining to response fluctuations (see appendix protocol)

Study description

Background summary

Anxiety syndromes are common in patients with Parkinson*s disease (PD) with up to 30% suffering from panic disorder, and up to 11% from generalized anxiety disorder. Other anxiety disorders occur with a lower prevalence. Anxiety in PD is associated with increased subjective motor symptoms, more severe gait problems and dyskinesias, as well as with freezing and on/off fluctuations. Anxiety symptoms in PD patients have also been shown to have a negative impact on health related quality of life.
The study of the prevalence, phenomenology and treatment of anxiety syndromes

in PD has been hampered by a lack of validated rating scales. Whereas validation of depression rating scales has received much attention in PD, a systematic review of anxiety rating scales commissioned by the Movement Disorder Society recently showed that none of the commonly used anxiety rating scales have been properly clinimetrically evaluated. Since clinimetric properties of ratings scales depend upon the population they are used in, state of the art research requires that rating scales are validated for the specific research populations, such as in this case: PD patients. This validation is an imperative prerequisite for future studies assessing the efficacy of anxiety treatments in PD. In addition this study will yield information on theprevalence and symptomatology of anxiety disorders.

Study objective

The primary objective of this study is to assess the reliability and validity of the most commonly used anxiety rating scales in PD within one year. In the event that none of these scales has satisfactory clinimetric properties, additional exploratory analysis at item level will be performed to identify the most important items for inclusion in a new anxiety scale, specific to PD, which then will require further validation.
The secondary objectives are to study the prevalence and phenomenology of anxiety disorders in PD, including the description of atypical anxiety syndromes occurring in PD patients, and anxiety states associated with *off* periods or periods of dyskinesias in patients with response fluctuations.

Study design

This is a one year cross-sectional international multi-centre study involving 360 PD patients. Six centers in the United States (2), Europe (3) and Australia (1) will participate and each include 60 patients.

Study burden and risks

no risks associated.

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

- Idiopathic Parkinson's Disease according to the Queens Square Brain Bank criteria
- Informed consent

Exclusion criteria

- patients with neurodegenerative disorders other than PD
- patients under 50 years of age
- dementia or severe cognitive decline, operationalised as an Mini Mental State Exam score < 23

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	29-10-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL24642.068.08