Comorbidity and Aging in Rehabilitation Patients: the influence on Activities; substudy Parkinon's disease, follow-up after 8, 10, 12 and 15 years

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The aim is to further track the course of motor symptoms and functional status, and to establish conversion to Parkinson*s disease dementia (PDD).

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

Summary

ID

NL-OMON38573

Source
ToetsingOnline

Brief title
CARPA-PD 8-10-12-15

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Michael J Fox-foundation;additionele

financiering bij Parkinon Vereniging aangevraagd

Intervention

Keyword: cohort, Parkinson, prognosis

Outcome measures

Primary outcome

To describe the progression of PD in the following domains: motor impairments, cognitive dysfunction (including conversion to Parkinson*s Disease Dementia), disability, and quality of life.

Secondary outcome

1. To identify clinical variables that are prognostic factors in the abovementioned domains.

2. To describe mortality and the need for admission in residential care in PD patients, and the degree to which this is a direct consequence of PD.

Study description

Background summary

There is considerable variation in the clinical course of Parkinson*s disease (PD) between individual patients. In clinical practice, the heterogeneity of PD impedes the adequate counseling of patients about the prognosis of the disease, and it may lead to diagnostic difficulties. In the clinical research setting, the heterogeneity of PD has consequences for samples sizes needed in clinical trials. The recent surge of interest in neuroprotective therapies has further increased the demand of data on the clinical course of PD and its possible prognostic factors. There are numerous studies describing the progress of the disease, and synthesized data from systematic reviews are available. The reviews pointed towards older age at onset and a postural instability and gait difficulty (PIGD) phenotype at baseline as prognostic factors for worse progression of disability. They found conflicting or limited evidence for other prognostic factors of motor impairments and disability. Furthermore, they concluded that research on the progression of PD to date is not fulfilling the

high standards applied nowadays. Main critiques on available studies were the use of prevalent cases or patients who were originally enrolled in a therapeutic trial, which both can lead to selection bias with an underestimation of disease progression. In addition, the majority of available studies had a relatively short duration of follow up. To gather more data on the clinical course and to identify prognostic factors for disease progression in an unbiased cohort of PD patients the CARPA-project was initiated eight years ago.

Study objective

The aim is to further track the course of motor symptoms and functional status, and to establish conversion to Parkinson*s disease dementia (PDD).

Study design

At baseline and after 1, 2, 3, and 5 years a set of rating scales and questionnaires was used for assessment of disease progression. We intend to use the same set at the follow-up visits at 8, 10, 12 and 15 year.
This set will be extended with the Parkinson Disease * Cognitive Rating Scale (PD-CRS) to increase sensitivity for Parkinson*s Disease Dementia (PDD).
- Unified Parkinson Disease Rating Scale;
- Hoehn and Yahr scale;
- Cumulative Illness Rating Scale (comorbidity);
- Schwab and England Activities of Daily Living Scale;
- Functional Independence Measure and the AMC Linear Disability Score;
- PD Quality of Life questionnaire (PDQL) and Short Form Health Survey (SF-36);
- Mini Mental State Examination (MMSE);
- Parkinson Disease * Cognitive Rating Scale (PD-CRS)
- Hospital Anxiety and Depression Scale (HADS).

For the diagnosis of PDD, we will use the diagnostic procedure as proposed by the Movement Disorders Society. In case of diagnostic doubt, a neurologist specialized in movement disorders will contact the treating neurologist, or if necessary, will visit the patient for neurological evaluation.
Annual disease progression and the impact of prognostic factors will be described using linear mixed models for continuous data. The proportion of demented patients at each follow-up visit will be reported, and the influence of prognostic factors will be analyzed using logistic (or Cox) regression analysis. The proportions of deceased patients will be reported using descriptive statistics, and the influence of prognostic factors will be analyzed using Cox proportional hazards model.

Study burden and risks

Each assessment will take about one to two hours. All patients will be visited at their home. If individual patients experience a home visit as inconvenient

we will offer to perform the assessment at the out-patient clinic. The study visit comprises of a brief physical and cognitive examination, and the filling in of health related questionnaires. Study participants are therefore not exposed to health-related risks. If a participant experiences the visit as inconvenient (eg. due to cognitive dysfunction), the visit will be shortened. The proposed study will lead to a total follow-up period of 15 years from the moment of diagnosis. It will render data on the conversion to dementia, progression of motor and cognitive symptoms, and its impact on disability and quality of life in mid-term to late stage PD. Prognostic models can be made using the data that are already available from the earlier follow-ups. In this way, the value of the baseline assessment and neuropsychological follow-ups performed earlier in the study will increase. The data from this project will be directly ready to use for patient counselling regarding disease prognosis. Since the large variability in the clinical course of PD has been an important limiting factor in patient counselling, the identification of prognostic variables in the present study will improve the predictions of prognosis for individual patients. In addition to the direct benefit for patient counselling, the knowledge about the clinical course of PD can also lead to an increased efficiency of future clinical trials.

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

Participation in the CARPA-study up till five years

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2013
Enrollment:	89
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2013
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL44474.029.13