

**The prodromal phase of Parkinson's Disease; Symptoms, duration, health care resource use and costs over a 5-year period prior to the diagnosis is made.**

**De vroege beginfase van de ziekte van Parkinson; Symptomen, duur, zorgconsumptie en gezondheidszorgkosten in de 5 jaar voorafgaande aan het stellen van de diagnose.**

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON27525

### Source

NTR

### Health condition

Idiopathic Parkinson's Disease, preclinical phase, health care resource use, costs

Ziekte van Parkinson, preklinische fase, zorgconsumptie, gezondheidszorgkosten

## Sponsors and support

**Primary sponsor:** Atrium Medisch Centrum Parkstad

**Source(s) of monetary or material Support:** Atrium Medisch Centrum Parkstad

## Intervention

## Outcome measures

### Primary outcome

Information is obtained from medical records of General Practitioners, from hospital medical records and during a standardized interview with the patients. To ensure the accuracy of recall information during the interview, particularly for some patients with cognitive deficits, patients are asked to be accompanied by a caregiver. These information is obtained over a 5-year period prior the the year the diagnosis is made. Investigated will be the symptoms, the duration of the preclinical phase, the medical health care resource use and costs.

### Secondary outcome

Cost-predicting factors, for instance patient characteristics and medical health care resource use will be identified.

## Study description

### Background summary

The preclinical phase of idiopathic Parkinson's Disease can be accompanied by different aspecific symptoms and signs. Therefore the delay before diagnosis is made can last months to years. It is expected that the total economic burden of this preclinical phase is high; however, the exact costs are not known. This retrospective study will investigate the symptoms, duration, health care resource use, costs and cost-predicting factors in the 5-year period prior to the diagnosis idiopathic Parkinson's Disease is made. The aim of this study is to increase knowledge about the impact of the preclinical phase. Further more, health practitioners might be able to make an earlier diagnosis and start the correct therapy as soon as possible.

Countries of recruitment: The Netherlands.

## Study objective

Idiopathic Parkinson's Disease is a chronic progressive neurodegenerative disorder. The preclinical phase of the disease is accompanied by different motor and non-motor symptoms and signs. These symptoms can occur even 5-8 years before classical motor symptoms develop and are sometimes very aspecific. Therefore the delay before diagnosis can last months to years. It is expected that this prodromal phase is associated with significant health care resource burden and costs due to outpatient care, inpatient care, drugs, diagnostic investigations and professional home care. Also production loss due to long-term sick-leave and early retirement and informal care give significant burden on families and society. It is expected that the total economic burden of this preclinical phase is high; however, the exact costs are not known. This retrospective study will investigate the symptoms, duration, health care resource use and costs of the preclinical phase in patients with idiopathic Parkinson's Disease over a 5-year period prior to the diagnosis is made. These economic burden shall be compared with age matched control subjects. The aim of this study is to increase knowledge about the impact of this preclinical phase. Further more, health practitioners might be able to make an earlier diagnosis and start the correct therapy as soon as possible.

## Study design

The information is obtained over a 5-year period prior to the year the diagnosis idiopathic Parkinson's Disease is made.

## Intervention

None.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

1. Idiopathic Parkinson's Disease according to the U.K. Parkinson's Disease Society Brain Bank Criteria;
2. Diagnosis made in 2007, 2008, 2009 or 2010;
3. Written informed consent.

### Exclusion criteria

Atypical Parkinson's Disease (for instance vascular parkinsonism, drug-induced parkinsonism, multiple system atrophy, corticobasal degeneration, progressive supranuclear palsy).

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-03-2010
Enrollment:	150
Type:	Anticipated

## Ethics review

Positive opinion

Date: 20-04-2010

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	NL2171
NTR-old	NTR2295
Other	METC Atrium-Orbis-Zuyd : 10-N-30
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A