

# Causes of drooling in Parkinson's disease

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To demonstrate the likelihood of the motor causes of drooling in PD: reduced swallowing frequency (akinesia), open mouth and mouth breathing (rigidity), reduced swallowing capacity (hypokinesia) and stooped posture.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Movement disorders (incl parkinsonism)
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON31278

### Source

ToetsingOnline

### Brief title

Causes of drooling

### Condition

- Movement disorders (incl parkinsonism)

### Synonym

drooling, saliva control

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Sint Radboud

**Source(s) of monetary or material Support:** Ministerie van OC&W,eigen middelen vanuit marktgerichte activiteiten (scholing)

### Intervention

**Keyword:** Drooling, Parkinson's disease, pathophysiology

## Outcome measures

### Primary outcome

Statistically significant differences between the two groups concerning swallowing frequency, swallowing capacity and breathing pattern.

### Secondary outcome

Not applicable

## Study description

### Background summary

Loss of saliva (drooling) is a frequent complaint in patients with Parkinson's disease (PD), reported by 30% or more. Current treatments are aimed at diminishing saliva production, mostly by injections with botulinum toxin in the saliva glands. Increasing evidence suggests that drooling is not caused by hypersecretion, but is due to motor disorders, typical for PD-patients. Possibly these causes could be treated using behavioral techniques.

### Study objective

To demonstrate the likelihood of the motor causes of drooling in PD: reduced swallowing frequency (akinesia), open mouth and mouth breathing (rigidity), reduced swallowing capacity (hypokinesia) and stooped posture.

### Study design

Observational (enriched cohort study). PD-patients with daily drooling and PD-patients without any complaints about drooling are recruited after regular assessment at the movement disorders clinic and asked to fill in a questionnaire to assess severity. All patients are observed with the same measures: the swallowing frequency is measured with surface EMG electrodes on the floor of the mouth and the larynx and the airflow near the nose is measured, while the patient is relaxing in a chair during 45 minutes. Subsequently, breathing capacity is measured with a spirometer and salivaproduction with a known swab technique, during 2 minutes.

### Study burden and risks

Burden for the patient: self-administered questionnaire of 7 items and watching tv for 45 minutes without a pause and without drinking or eating.  
Risks: none.

## 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

Confirmed diagnosis of Parkinson's disease or parkinsonism

Complaints of moderate or severe drooling OR no complaint about saliva control at all.

Stable regime of anti-parkinson medication.

Ability to sit in a chair for min. 75 minutes.

## Exclusion criteria

Mild or unclear complaints about drooling  
Unable to follow instructions

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2007

Enrollment: 30

Type: Anticipated

## Ethics review

Approved WMO

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

## 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	NL19569.091.07