# Feasibility study of saliva swallowing frequency measurements using 24-hours ambulatory impedance-pH monitoring in patients with Parkinson\*s disease and drooling.

Published: 03-06-2015 Last updated: 16-04-2024

To assess the feasibility and burden of the 24-hAlpHM to precisely measure saliva swallowing frequency during everyday life in PD patients.

Ethical review Approved WMO

**Status** Pending

**Health condition type** Movement disorders (incl parkinsonism)

**Study type** Observational invasive

## **Summary**

#### ID

**NL-OMON41751** 

#### Source

ToetsingOnline

#### **Brief title**

24 hr saliva swallowing frequency measurement in Parkinson\*s disease.

## **Condition**

Movement disorders (incl parkinsonism)

## **Synonym**

drooling

## **Research involving**

Human

## **Sponsors and support**

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

Source(s) of monetary or material Support: Ministerie van OC&W

## Intervention

**Keyword:** drooling, impedance-pH, Parkinson's disease, saliva swallowing frequency

## **Outcome measures**

## **Primary outcome**

Criteria for feasibility: 4 out of 5 patients indicate that operating the data

logger is feasible, report no or acceptable burden and no adverse events.

Total costs, including time for manual counting of spontaneous swallows during

24 hour.

## **Secondary outcome**

NA

# **Study description**

## **Background summary**

A quarter of patients with Parkinson\*s disease (PD) suffer from involuntary loss of saliva or drooling, which is a disabling and still undertreated symptom. Precise measurement of saliva swallowing frequency (SSF) related to the drooling events is essential to better understand the pathophysiology of drooling and to evaluate and explain the effects of (new) behavioral treatment approaches. SSF should be measured in everyday life to catch any change in SSF before and during drooling events at home. Non-invasive measurements of SSF are either limited in time or location or are still interfered with other upper airway sounds or body movements. However, 24-hours ambulatory impedance-pH monitoring (24-hAlpHM), a common gastroenterological measurement is a suitable instrument for SSF registration, but its feasibility and burden for the registration of SSF in PD patients with drooling had not been studied yet.

## Study objective

To assess the feasibility and burden of the 24-hAlpHM to precisely measure saliva swallowing frequency during everyday life in PD patients.

## Study design

Observational study.

## Study burden and risks

24-hAlpHM is an invasive, but common and low risk measurement. The burden is reported to be low, but it is important to know whether this is also true for PD patients. The extra burden is coming to the Radboudumc twice and completing a questionnaire once. The future benefit is the possibilty of having more treatment options for drooling.

## **Contacts**

#### **Public**

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# **Trial sites**

#### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

### Age

Adults (18-64 years)

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Elderly (65 years and older)

## Inclusion criteria

Patients diagnosed with Parkinson's disease or with an atypical parkinsonism irrespective of Hoehn & Yahr stage.

Patients with slight to severe complaints about saliva control or drooling.

Patients who are able to cooperate in the protocol.

## **Exclusion criteria**

Any medical treatment of drooling causing hyposalivation.

Suspected or confirmed pharyngeal or upper esophageal obstruction.

Severe coagulopathy, outside the therapeutic range when applicable.

Presence of any structural abnormality of the esophagus which theoretically may be associated with an increased risk of side effect or hamper the intubation. These includes peptic strictures, ulcers, tumors, varices or large diverticula.

Cardiac conditions such as a previous episode of bacterial endocarditis, heart valve replacement, implantable cardiac defibilator or pacemaker, or any cardiac condition in which vagal stimulation is poorly tolerated.

# Study design

## **Design**

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

#### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2015

Enrollment: 5

Type: Anticipated

# **Ethics review**

Approved WMO

Date: 03-06-2015

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 NL52490.091.15