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

Study design

Observational study.

Study burden and risks

24-hAIpHM 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

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