Dysphagia in Huntington's disease. The development of the Huntington's Disease Dysphagia Scale.

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The aim of the study is to generate a validated questionnaire to measure dysphagia in the three different stages of Huntington's disease.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Chromosomal abnormalities, gene alterations and gene variants
Study type	Observational invasive

Summary

ID

NL-OMON37730

Source
ToetsingOnline

Brief title
Dysphagia in Huntington's disease.

Condition

- Chromosomal abnormalities, gene alterations and gene variants
- Movement disorders (incl parkinsonism)

Synonym
Dysphagia; swallowing disorder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Jacques en Gloria Gossweiler foundation

Intervention

Keyword: dysphagia, Huntington's disease, questionnaire

Outcome measures

Primary outcome

To validate the questionnaire videofluoroscopic examination will be used.

In order to measure convergent construct validity the questionnaire will be compared with the Swallowing Disturbance Questionnaire (SDQ), and the Eating Assessment Tool (EAT-10). Partners or relatives will be asked to fill in the questionnaires simultaneously with the patients.

Secondary outcome

na

Study description

Background summary

Most patients with Huntington's disease suffer from dysphagia. Dysphagia has influence on the quality of life for the patients, but can also have physical consequences, like pneumonia. Research demonstrates that more than a half of the patients die from pneumonia due to dysphagia. It is therefore very important to find out when dysphagia in Huntington's disease starts, and how it progresses. In this study a scale will be created, especially for Huntington's disease patients, which measures the severity of the dysphagia in the disease. When it is known when dysphagia in Huntington's disease starts, and how it progresses, intervention studies can be set up. Patients can also be better treated because of the more precise knowledge on dysphagia in Huntington's disease.

Study objective

The aim of the study is to generate a validated questionnaire to measure dysphagia in the three different stages of Huntington's disease.

Study design

The study will be divided into two phases:
phase 1
- generate a sample of questions related to Huntington's disease and dysphagia at the level of disability
- investigate intelligibility of the questions and the response options

phase 2
- test-retest the questionnaire in the three clinical stages of Huntington's disease
- item reduction and scale construction
- validation of the questionnaire

Study burden and risks

It is stated that participation in this study the risks can be considered negligible, and the burden minimal. The average effective dose for videofluoroscopy is 1 mSv per test. To compare: videography of the thorax gives a dose of 0.09 mSv, and a scan of the abdomen gives a dose of 10 mSv. A year dose as result of background radiation in the Netherlands is 2 mSv. Videofluoroscopy is not stressful, patients will not receive any tubes.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef P.O. Box 9600
2300 RC Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef P.O. Box 9600
2300 RC Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Huntington's disease patients, CAG over 36 repeats.

Exclusion criteria

Other diseases or conditions that may influence swallowing.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-06-2012
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	02-05-2012
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL39192.058.12