

The timed Swallowing Performance EATing and drinking (SPEAT) test to objectify dysphagia in head and neck cancer patients

Published: 30-03-2018

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Primary Objective: To evaluate the feasibility and test-retest reliability of the Swallowing Performance EATing and drinking (SPEAT)-test in assessing swallowing function. Secondary Objectives: - To explore the intra- and inter-rater reliability and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON48822

Source

ToetsingOnline

Brief title

SPEAT-test als maat voor dysfagie

Condition

- Other condition

Synonym

Dysphagia, swallowing problems

Health condition

Slikproblemen

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

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

Intervention

Keyword: Dysphagia, speed, swallowing, test

Outcome measures

Primary outcome

Feasibility and test-retest reliability of the SPEAT-test.

Secondary outcome

Inter- and interrater reliability and validity

Normal values of the SPEAT-test among healthy individuals within the age range of head and neck cancer patients.

Study description

Background summary

Despite the wide range of possible assessment methods for swallowing function, the correlation between the objective and subjective assessment methods seem poor. This suggests that the present objective tools do not assess the same aspects of swallowing and eating in daily life as the subjective measures. As an extension of the timed 100mL water swallow test (WST), we developed the Swallowing Performance EATing and drinking (SPEAT)-test which includes the measurement of time needed to consume three boluses of different consistencies. It is an easily accessible test, requiring minimal equipment and time and can possibly be used to objectify, evaluate and monitor swallowing function as well as giving insight in the participation level (ICF-code) of eating and drinking in daily life.

Study objective

Primary Objective: To evaluate the feasibility and test-retest reliability of

the Swallowing Performance EATing and drinking (SPEAT)-test in assessing swallowing function.

Secondary Objectives:

- To explore the intra- and inter-rater reliability and validity of the SPEAT-test.
- To explore the normal values of the SPEAT-test among healthy individuals within the age range of head and neck cancer patients.

Study design

In order to evaluate the reliability, the SPEAT-test will be performed in 80 subjects of which 40 have swallowing problems and 40 are healthy volunteered. Each subject will perform the test three times and a film recording of one test will be evaluated three times. Also, outcome measures will be collected in order to evaluate validity of the test.

Study burden and risks

The burden to the patient mainly includes the time it takes to complete the assessment which is 75 minutes.

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 treated for head and neck cancer
- Patients who will receive a videofluoroscopy as part of standard care
- Patients with dysphagia according to the Speech Language Pathologist

Exclusion criteria

No (history of) swallowing problems

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-07-2018
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date: 30-03-2018

Application type: First submission

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO

Date: 16-08-2019

Application type: Amendment

Review commission: PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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

CCMO

ID

NL62178.031.17