Muscle activation during strengthening exercises with the Swallow Exercise Aid: visualization with Magnetic Resonance Imaging.

Published: 15-05-2018
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To visualize the muscles activated during standard exercises performed with the Swallow Exercise Aid by means of T2 mapping with Magnetic Resonance Imaging.

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

Summary

ID

NL-OMON46505

Source
ToetsingOnline

Brief title
Visualization of muscle activation with MRI

Condition

- Other condition

Synonym
No condition is investigated

Health condition

Slikproblemen na hoofd-halskanker

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: MRI, Swallowing exercises

Outcome measures

Primary outcome

T2-value change in possible involved muscles after three exercises with the

SEA.

Secondary outcome

Not applicable

Study description

Background summary

The Swallow Exercise Aid (SEA) was developed as a tool for muscle strengthening exercises to restore swallowing function after head and neck cancer treatment. However, there are insufficient data to prove that the training program targets all relevant swallowing muscles. This information is needed to optimize the training program. Muscle functional Magnetic Resonance Imaging (mfMRI) is a non-invasive technique which can be used to visualize activated muscles after exercise.

Study objective

To visualize the muscles activated during standard exercises performed with the Swallow Exercise Aid by means of T2 mapping with Magnetic Resonance Imaging.

Study design

Pretest-posttest study

Study burden and risks

The burden to the study subject mainly includes the time it takes to participate: three times an MRI of 20 minutes. The MRI itself is not accompanied with health risks. The participant him-/herself will not benefit from participating in this study. However, information on whether the training program targets all relevant swallowing muscles is relevant for dysphagia patients. This information can be used to optimize the training program.

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

- Healthy volunteers with no altered anatomy of the head and neck area
- Participants at least 18 years old

Exclusion criteria

- Participants with a contra-indication for the MRI (e.g. pacemaker, claustrophobia)
- Participants with material in the head and neck area that might disturb the images of the target muscles (e.g. braces)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-08-2019
Enrollment:	4
Type:	Actual

Ethics review

Approved WMO Date:	15-05-2018
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	18-06-2019
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	ID
CCMO	NL64540.031.18