

Prospective assessment of swallowing and speech function 10 years after preventive swallowing rehabilitation and chemoradiotherapy for head and neck cancer

Published: 13-12-2017

Last updated: 10-08-2024

To assess swallowing and speech function in patients ten years after CRT for head and neck cancer with preventive rehabilitation in order to compare these results with those after six years and to those of patients after CRT without preventive...

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

Summary

ID

NL-OMON44230

Source

ToetsingOnline

Brief title

Swallowing and speech functie 10 years after preventive rehabilitation

Condition

- Other condition

Synonym

Swallowing and speech impairment

Health condition

Functionele beperkingen op het gebied van slikken en spreken.

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: Head and neck cancer, Preventive rehabilitation, Speech, Swallowing

Outcome measures

Primary outcome

- Objective swallowing outcomes

o Videofluoroscopy

o Other parameters: tube dependency/nutritional supplements, Functional Oral

Intake Scale (FOIS), weight change/BMI, maximal inter-incisal opening (MIO),

symptom specific questions, pain (VAS)

- Objective speech outcomes

o Speech recordings

- Subjective outcomes

o SWAL-QOL

o Voice Handicap Index

o Speech Handicap Index

o EORTC QLQ-C30 and H&N35

o EQ-5D-5L

o Study specific questions

Secondary outcome

Not applicable

Study description

Background summary

Despite good results on survival, chemoradiotherapy (CRT) for head and neck cancer is associated with substantial short- and long-term toxicities. In order to prevent these toxicities from occurring, multiple studies have investigated preventive rehabilitation strategies. Results on these strategies show effectiveness on functional outcomes. However, since functional outcomes can deteriorate years after CRT, long-term results are essential to provide information regarding the effectiveness of preventive exercises in head and neck cancer survivors.

Study objective

To assess swallowing and speech function in patients ten years after CRT for head and neck cancer with preventive rehabilitation in order to compare these results with those after six years and to those of patients after CRT without preventive rehabilitation.

Study design

Prospective observational cohort study

Study burden and risks

The primary burden for the individual patient is the time it takes to complete the assessments (70 minutes). The main risk involves the added (relatively low) radiation exposure during the videofluoroscopy.

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

Evaluable and disease-free head and neck cancer survivors who participated in the randomized controlled trial regarding a preventive rehabilitation program during chemoradiotherapy, performed ten years ago.

Exclusion criteria

(suspected) recurrent head and neck cancer

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 31-05-2018
Enrollment: 22
Type: Actual

Ethics review

Approved WMO
Date: 13-12-2017
Application type: First submission
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 | NL63465.031.17 |