Prediction of Radiation-induced Swallowing Dysfunction after Curative (Chemo)Radiation for Head and Neck Cancer

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON31538

Source
ToetsingOnline

Brief title
SLIK study

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
dysphagia, swallowing complaints

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Head and neck cancer, Predictive model, Radiotherapy, Swallowing dysfunction

Outcome measures

Primary outcome

Grade 2 or more swallowing dysfunction at 6 months after completion of

(chemo)radiation (according to the RTOG/EORTC system).

Secondary outcome

• Findings of videofluoroscopy.

• Dysphagia, Esophageal Morbidity and Aspiration according to the Common

Terminology Criteria for Adverse Events version 3.0.

• Thickening of the pharyngeal constrictor muscles, the pharyngeal and

laryngeal mucosa on CT-scan

• Health related quality of life (EORTC QLQ-C30 and EORTC QLQ-H&N35)

• Patient-rated swallowing complaints (SWAL-QoL)

Study description

Background summary

Swallowing dysfunction after curative (chemo)radiation is a frequently reported side effect which has a major impact on health related quality of live, probably even more important than radiation-induced xerostomia.
The results of clinical studies identified a number of possible pathophysiological mechanisms that contribute to the development of radiation-induced swallowing dysfunction, which are most likely to result from fibrosis of the pharyngeal muscles and swelling of the pharyngeal and laryngeal

mucosa. Subsequently, the results of other studies strongly suggest that the dose distribution in the pharyngeal muscles and laryngeal structures are significantly associated with the probability of swallowing dysfunction. Consequently, sparing of these structures could result in reduce the risk on this important side effect.

Study objective

The first objective is to assess which determinants predict swallowing dysfunction after curative (chemo)radiation. We want to determine the possible relationships between the radiation dose distributions in anatomical structures involved in swallowing and the probability of swallowing dysfunction.
The second objective is to determine which pathophysiological mechanisms are involved in the development of swallowing dysfunction after (chemo)radiation by using objective measures, including pre- and post-treatment videofluoroscopy and CT-scan.
The final objective will be to determine which endpoint regarding swallowing is the most relevant.

Study design

This is a prospective cohort study

Study burden and risks

Additional investigations for this study will be patient-rated swallowing complaints, videofluoroscopy findings and thickening of the pharyngeal constrictor muscles, pharyngeal mucosa and laryngeal mucosa as assessed by CT of the head and neck region.
The burden of this study will be only minimal. Participating patients will receive approximately 7 mSv extra radiation dose. However, patients will receive at least 70000 mSV during radiotherapy treatment. Additional ionizing radiation exposure due to the CT-scan and videofluoroscopy will therefore be relatively small. Videofluoroscopy will take approximately 20 minutes, CT-scan will take 20 minutes and every additional questionnaire will take 5 minutes to complete.

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

- primary head and neck cancer (or lymph node metastases from an unknown primary)
- stage I-IV (UICC staging system 2002)
- no distant metastases
- no postoperative radiotherapy / chemo-radiotherapy
- previously untreated

Exclusion criteria

- distant metastases
- surgery

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-06-2008
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL21049.042.07