Normalcy of food intake in head and neck cancer patients receiving radiotherapy supported by swallowing therapy and individual dietary councelling.

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To improve normalcy of food intake (food quantity and quality, decrease use of tube feeding/ nutritional supplements) in patients with head and neck cancer with pre-, per- and post treatment radiotherapy due to individually tailored swallowing...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Appetite and general nutritional disorders
Study type	Interventional

Summary

ID

NL-OMON32939

Source
ToetsingOnline

Brief title
FOCISD-study

Condition

- Appetite and general nutritional disorders
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Dysphagia in Head and neck neoplasms, swallowing problems in head and neck cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Fresenius Kabi ,Sorgente BV (Facilitair bedrijf),Sorgente BV en Fresenius Kabi

Intervention

Keyword: Head and neck cancer, normalcy of food, Radiotherapy, Swallowing therapy

Outcome measures

Primary outcome

-Quality of food intake (based on food modifications)

-Use of tube feeding/diet supplements

Secondary outcome

-Quality of Life

-Nutritional status

Study description

Background summary

Oral nutrition appears to be a challenge for patients with head and neck cancer (HNC patients) after radiotherapy. Many patients desire to their usual food intake and to return to oral nutrition with normal consistency (without modifications) but due to the swallowing problems experienced post treatment this seems tremendously difficult. Referral to a speech therapist is not a standard procedure in the RUNMC as part of pre-, -per and post-treatment radiotherapy. Swallowing intervention might support nutritional intervention and in that way improve quantity and quality of food intake, reduce the need for tube feeding.

Study objective

To improve normalcy of food intake (food quantity and quality, decrease use of tube feeding/ nutritional supplements) in patients with head and neck cancer with pre-, per- and post treatment radiotherapy due to individually tailored swallowing therapy by an experienced speech-language therapist in cooperation

Individual dietary councelling by an experienced dietician.

Secondary objectives are:
-patients quality of life
-nutritional status.

Study design

A prospective, randomized study will be carried out at the department of Radiotherapy, Rehabilitation and Gastroenterology - dietetics, RUNMC. One group will receive individualized swallowing therapy by a speech-language therapist (SLT), pre-, per- and post treatment in cooperation with extensive dietary councelling by a specialized dietician. The other group will have standard usual care for head and neck cancer patient treated with radiotherapy including extensive dietary councelling by a specialized dietician.

Intervention

The experimental group will be monitored and treated (when needed) by an experienced SLT to compensate for any consequence of the tumor or adverse event of the radiotherapy on the efficiency or safety of oropharyngeal swallowing, as is recommended by the Dutch guidelines. The monitoring and interventions will start as soon as the radiotherapy has been decided and planned, until 6 months after the last radiotherapy session. To further optimize the efficacy and efficiency of the rehabilitation the SLT cooperates closely with an experienced dietician by protocol, to ensure that every patient receives the most suitable nutritional advice at every moment from pre-radiotherapy until 6 month after radiotherapy.

Study burden and risks

Not applicable

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

1. Patients >= 18 years.
2. Patients with tumor in Oral cavity, nasopharynx, oropharynx, hypopharynx or larynx with tumor stage II-IV (UICC TNM-tumor classification)
3. Eligible for primary curative treatment intentions with (chemo)radiation or adjuvant radiotherapy
4. A signed informed consent.

Exclusion criteria

1. Historical swallowing problems (neurological or not tumor related).
2. Unable to comprehend and carry out the swallowing intervention.
3. Unable to answer study questionnaires. (illiterate)
4. Radiation or surgery for Head and neck cancer in history.

Study design

Design

Study phase: 2

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2010
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	26-02-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL28638.091.09