Prognostic counselling in head and neck cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27751

Source
Nationaal Trial Register

Health condition

Head and Neck Squamous Cell Carcinoma
Prognostic
Counselling
Decisional Conflict
Quality of Life
Hoofd-hals kanker
Prognostiek
Voorlichten
Kwaliteit van Leven

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam The Netherlands
Source(s) of monetary or material Support: Erasmus Medical Center Rotterdam The Netherlands
Stichting Theia Achmea Health

Intervention

Outcome measures

Primary outcome

The fraction of patients who choose not to follow RWHHT advice and therefore receive a non-protocol based treatment

Secondary outcome

- Decisional conflict

- Quality of life

- (Disease-free) survival rates: recurrence of the tumor, death and cause of death.

Study description

Background summary

Background:

In the Netherlands, about 2700 new patients with head and neck squamous cell carcinoma (HNSCC) are diagnosed annually. In the majority of cases, treatment consists of surgery, radiotherapy, chemotherapy and combinations of these modalities. All types of treatment are associated with high morbidity, sometimes compromising vital functions. Accurate counselling for treatment options, survival rates and quality of life is therefore important. Without the knowledge of a reliable individual prognosis, the patient and doctor both will tend to choose treatment according to protocol-based advices by a multidisciplinary team, which is usually the most extensive treatment. Extensive treatment is often associated with major morbidity. While, in patients with a poor prognosis, survival rates will not increase substantially following aggressive treatment. Especially in these patients, the balance between survival and quality of life could be improved by choosing a less aggressive and non-protocol based treatment. Our hypothesis is that a change to individualized prognostic counselling leads to less decisional conflict, less extensive treatment, and an improved quality of life in patients with HNSCC.

Methods:

In a prospective clinical trial with sequential cohorts we want to investigate the influence of prognostic counselling in patients with HNSCC. For this purpose, the departments of Otorhinolaryngology – Head and Neck Surgery of the Erasmus MC and of the Leiden University Medical Center developed during the last decade dedicated software packages

incorporating a prognostic model, in which an individualized prognosis for each patient with HNSCC can be calculated (OncologIQ). Besides localisation and TNM-classification of the tumor, patient characteristics such as gender, age, medical history and comorbidity (ACE-27) are taken into account. The outcome of this calculation is expressed in a time-bound percentage (as for example 5-year survival rate), applicable for that specific patient. This prognostic model is internally and externally validated. Newly diagnosed patients with HNSCC at Erasmus MC, with a curative intent, will be included. Prognosis will be communicated using absolute percentages visually supported by graphics. Questionnaires on decisional conflict, quality of life and decisional regret will be taken to measure outcomes.

Conclusion:

In an era of shared decision making, personalized medicine and focus on quality of life, we should not avoid the dialogue between patient and doctor about their prognosis using facts and figures. In our opinion individualized prognostic counselling, using unique patient characteristics, will support informed values based decisions, and therefore will lead to improved communication and quality of life. One should not be afraid of making nonstandard treatment choices in shared decision making when major morbidity or even mortality and a significant decrease in quality of life could be avoided. With the implementation of our innovative prognostic model, OncologIQ, in clinical practice for patients with HNSCC, we aim to improve communication and quality of life: in other words, true personalized medicine.

Study objective

In the Netherlands, about 2700 new patients with head and neck squamous cell carcinoma (HNSCC) are diagnosed annually. In the majority of cases, treatment consists of surgery, radiotherapy, chemotherapy and combinations of these modalities. All types of treatment are associated with high morbidity, sometimes compromising vital functions. Accurate counselling for treatment options, survival rates and quality of life is therefore important. Without the knowledge of a reliable individual prognosis, the patient and doctor both will tend to choose treatment according to protocol-based advices by a multidisciplinary team (RWHHT), which is usually the most extensive treatment. Extensive treatment is often associated with major morbidity. While, in patients with a poor prognosis, survival rates will not increase substantially following aggressive treatment. Especially in these patients, the balance between survival and quality of life could be improved by choosing a less aggressive and non-protocol based treatment. Our hypothesis is that a change to individualized prognostic counselling leads to less decisional conflict, less extensive treatment, and an improved quality of life in patients with HNSCC.

Study design

Outcomes will be measured by obtaining several questionnaires on decisional conflict, shared decision making and quality of life.

- At time of diagnosis of HNSCC patients will answer questionnaires on medical history (ACE27), quality of life (EORTC-QLQ30, EORTC-H&N35, EQ5D) and anxiety (HADS).

- After 1 week, a prognosis and decision consultation will follow. Included patients will answer 2 questionnaires on decisional conflict (Decisional Conflict Scale and Control Preferences Scale).

- 3 months after their treatment included patients will answer questionnaires on Quality of Life (EORTC QLQ 30, EORTC H&N35, EQ5D), on anxiety (HADS) and on decisional regret (Decisional Regret Scale). Patients will also answer a question about the exact therapy they got. The investigator will compare this answer with the medical records to investigate if this therapy was protocol based or not.

Intervention

The first cohort receives current prognostic counselling. The next cohort receives individualized prognostic counselling, calculated by OncologIQ, software on the computer.

Contacts

Public
'S GRAVENDIJKWAL 230
E.A.C. Dronkers
Rotterdam 3015 CE
The Netherlands
Scientific
'S GRAVENDIJKWAL 230
E.A.C. Dronkers
Rotterdam 3015 CE
The Netherlands

Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Primary squamous cell carcinoma of lip, nasopharynx, oral cavity, oropharynx, larynx or hypopharynx

- Second primary squamous cell carcinoma of lip, nasopharynx, oral cavity, oropharynx, larynx or hypopharynx

- Treatment takes place in the Erasmus MC

- Written informed consent from the patient

- Age >= 18 years

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- No curative intent based on tumor site and tumor characteristics

- Recurrent tumor

- Simultaneous or synchronic multiple primary HNSCC

- Illiterate patient

- Insufficient knowledge of Dutch language

- Incompetent (due to a.o. mental state) to consider their own treatment choice

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2013
Enrollment:	500
Type:	Anticipated

Ethics review

Positive opinion
Date: 05-08-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47696
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3940
NTR-old	NTR4106
CCMO	NL42154.078.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON47696

Study results

Summary results
N/A