A prospective clinical trial with sequential cohorts on the effect of individualized prognostic counselling on treatment decisions and quality of life in patients with head and neck cancer.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47696

Source
ToetsingOnline

Brief title
Prognostic counselling in head and neck cancer

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
head and neck squamous cell carcinoma

Health condition

plaveiselcelcarcinoom van het hoofd-hals gebied

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Stichting Theia

Intervention

Keyword: decision making, head and neck cancer, prognostic model, quality of life

Outcome measures

Primary outcome

* A significant reduction of decisional conflict in the intervention group.

Secondary outcome

* Fraction of patients who choose not to follow RWHHT advice and therefore

receive a non-protocol based treatment in the intervention group.

* Quality of life: level of quality of life, specified on head and neck cancer,

anxiety and/or distress.

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

death

* Socio-economic status: highest level of education, current profession and

postal code of the home address

Study description

Background summary

In the Netherlands, about 2700 new patients with head and neck squamous cell carcinoma (HNSCC) are diagnosed annually. In 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 important. Dedicated software packages incorporating prognostic models have proven to aid physicians in making accurate predictions of prognosis for the individual patient with HNSCC. Our hypothesis is that individualized prognostic counselling leads to less decisional conflict. In patients with a poor prognosis individualized prognostic counselling may lead less extensive treatment and an improved quality of life.

Study objective

To investigate decisional conflict, treatment choices, and quality of life in patients with HNSCC after individualized prognostic counselling, in comparison with the current prognostic counselling. Secondary objectives are to investigate (disease-free) survival rates in patients after individualized prognostic counselling, in comparison with the current prognostic counselling and to investigate the influence of socio-economic status on treatment choices, decisional conflict, quality of life and (disease-free) survival.

Study design

Prospective clinical trial with sequential cohorts.

Intervention

The individual prognosis is calculated by OncologIQ, software on the computer, which is able to calculate survival rates in each individual, by using tumor- and patient characteristics. Besides localization and TNM-classification of the tumor, also age, gender, past diseases and comorbidity (ACE-27) of the patient are taken into account. The calculation shows a patient-specific survival rate, expressed in time-bound percentages for 1, 2 and 5 years of survival.

Study burden and risks

The extra burden of a patient is restricted to answering 4 questionnaires (total of 27 questions).

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE

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Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion 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
Curative intent
Follow-up takes place in the Erasmus MC
Written informed consent from the patient

Exclusion criteria

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:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2014
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	28-05-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	28-09-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	25-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2019

Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27751
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42154.078.13
OMON	NL-OMON27751