prediction of survival in palliative patiënts with head neck cancer

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Primary: development of a prognostic model for head and neck cancer patients in the palliative phase.Secundary: comparison of the prediction of the survival of palliative patients by the treating physician with both the prediction of the model as...

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

Summary

ID

NL-OMON32322

Source
ToetsingOnline

Brief title
survival palliative H&N oncology patients

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
head and neck cancer

Health condition

palliatieve hoofdhalskanker patiënten

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

Intervention

Keyword: head and neck cancer, palliative, prediction, survival

Outcome measures

Primary outcome

survival

Secondary outcome

na

Study description

Background summary

Head and Neck oncology is a rare disease: it concerns 2000-2500 patients a year
in the Netherlands. The disease itself and the treatment are often very radical
and mutulating and visible for both the patient and his relatives. This
largely influences the self perception and the social functioning of the
patient. The mean 5-years survival is 50%. Sometimes recurrence of the disease
after treatment is curable, but often a palliative phase has te be chosen. This
phase of the disease is characterised by a long duration and is very disabling
for the patient due to losses of vital functions. Furthermore, during this
phase a large appeal is done to relatives and health care.
The exact duration of the palliative phase is hard to predict. This period is
characterised with uncertainty for the patient and his relatives and a hard
decision-making with respect to potential interventions for optimal quality of
life.
Prof Baatenburg de Jong (ENT, ErasmusMC) and colleagues have developed a
prognostic model for newly diagnosed patients with head and neck cancer. This
results in an accurate estimate of the survival. This model can however not be
used for a palliative patient because different factors probably play a role in
the survival of a palliative patient. Until now only a few studies have been
published to prognostic models in palliative patients.
With this study, we expect to be able to estimate the prognosis of a palliative
patient much more accurate. The patient (and his relatives) will have an

improved treatment and care and also the medical decision-making (utilisation of interventions aiming at highest quality of life) will improve.

Study objective

Primary:
development of a prognostic model for head and neck cancer patients in the palliative phase.

Secundary:
comparison of the prediction of the survival of palliative patients by the treating physician with both the prediction of the model as well as the real survival.

Study design

Prospective cohort-study collecting data systematically from the medical file and additional questionnaires.

Study burden and risks

The following items belong to the standard procedure of a palliative patient, anamnestic data, physical examination, estimation of the prognosis of the treating physician, VAS-score on pain, blood tests and a chest X-ray. Therefore the extra burden of a patient is restricted to answering standard questionnaires during a home visit.

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

Palliative adult patiënts with not curable head and neck cancer.

Exclusion criteria

Patient treated and followed in a different medical centre.

Study design

Design

Study type: Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2008
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO
Date: 14-07-2008

Application type: First submission

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

Approved WMO
Date: 05-12-2008

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

No registrations found.

In other registers

Register	ID
CCMO	NL22801.078.08