Netherlands Quality of Life and Biomedical Cohort Studies_Head and Neck Cancer

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory and mediastinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON50452

Source
ToetsingOnline

Brief title
NET-QUBIC_HNC

Condition

- Respiratory and mediastinal neoplasms malignant and unspecified

Synonym
head and neck cancer, head and neck neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: KWF Kankerbestrijding / Alpe d'HuZes

Intervention

Keyword: biomedical, cohort study, quality of life, survival

Outcome measures

Primary outcome

1) To describe the long term course of QoL from diagnosis to 5 years follow-up or death in newly-diagnosed HNC patients and their caregivers and to identify cancer-related, personal, genetic, biological, psychobehavioural, physical, lifestyle-related, and social determinants of QoL.

Secondary outcome

2) To determine the association between QoL and survival adjusted for relevant cancer-related, personal, genetic, biological, psychobehavioural, lifestyle-related, and social factors.

3) To build predictive models for long term QoL and survival of cancer patients.

4) To prospectively examine patients* and their caregivers' supportive care needs in all phases of the disease and the association with the long-term course of QoL.

5) To establish a large QoL database and biobank of tissue specimen, DNA, RNA, serum plasma, saliva and oral rinse, with integrated clinical information.

Study description

Background summary

In head and neck cancer (HNC), little is known about the long-term course of quality of life (QoL) in patients and their informal caregivers, and its determinants across the disease-span. New empirical evidence suggests that tumour- and patient-related biomarkers, psychosocial functioning, and lifestyle

are also associated with QoL and survival. These associations can be influenced by various cancer-related, personal, genetic, biological, psychobehavioural, lifestyle-related, and social factors. Comprehensive insight in all these factors assessed in a standardized manner is necessary to unravel these complex associations.

Study objective

The primary objective is 1) to describe the long-term course of QoL in HNC patients and their informal caregivers and to identify cancer-related, personal, genetic, biological, psychobehavioural, physical, lifestyle-related, and social determinants of QoL.
Secondary objectives are: 2) To determine whether the association between QoL and survival is direct or mediated by other variables, 3) To build predictive models for QoL and survival, 4) To prospectively examine supportive care needs in all phases of the disease, 5) To describe the long term course of QoL in informal caregivers, 6) To establish a large QoL database and biobank of tissue specimen, DNA, RNA, serum plasma and saliva, with integrated clinical information.

Study design

NET-QUBIC_HNC is a multicenter prospective cohort study on HNC patients and their informal caregivers.

Study burden and risks

There are no risks involved in this study for the participants (patients and their caregivers). Participation burden involves the time investment to complete the questionnaires and the measurements (physical tests, psychiatric interview, psychological function, speech recording).
Participants can choose to fill out the questionnaires via pen / paper or online. To reduce the burden for patients and their caregivers the measurements will be done at home. When the participant prefers to visit the hospital for the measurements, this is also an option. Traveling expenses will be covered.

To evaluate the feasibility and achievability of this cohort study we conducted a pilot study. In this study we included 15 patients who completed the baseline assessment. During the inclusion period (four months), 15 out of 26 (60%) patients agreed to participate. Less women participated, 13% in responders group versus 63% in non-responders group (p= 0.008). No other differences were found between responders and non-responders. Responders completed more than 95% of the questionnaires items, and rated the number of questions, time investment and intimacy as feasible, and the physical and psychological burden as low.
In conclusion we can say that the comprehensive baseline assessment in patients

with HNC was considered feasible and participation rates were sufficient.

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

Newly diagnosed head and neck cancer patients

Exclusion criteria

malignancies of the salivary glands, nasopharyngeal malignancies, lymphoma, skin malignancies, thyroid cancer; patients unable to understand the questions

or test instructions; no informed consent and severe psychiatric co-morbidities

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-03-2014
Enrollment:	1478
Type:	Actual

Ethics review

Approved WMO Date:	26-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-09-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	02-11-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL45051.029.13