PREDICTIVE MODELS FOR RADIATION-INDUCED SIDE EFFECTS IN HEAD AND NECK CANCER BASED ON SINGLE NUCLEOTIDE POLYMORPHISMS (SNP)

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

Summary

ID

NL-OMON50431

Source
ToetsingOnline

Brief title
HEAD&NECK SNP (HANS) study

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms benign

Synonym
normal tissue toxicity; radiation toxicity

Health condition

Toxiciteit radiotherapie in hoofd-halskanker patiënten

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: "Genome-wide association study", "Head and Neck neoplasms", "Polymorphism, "Toxicity", single nucleotide"

Outcome measures

Primary outcome

The primary endpoint will be RTOG grade 2 or higher late dysphagia.

Secondary outcome

The secundary endpoints will be RTOG grade 2 or higher acute dysphagia; acute mucositis; tube feeding dependency; salivary dysfunction (flow); RTOG grade 2-4 acute/late xerostomia; osteoradionecrosis; hypothyroidism; patient-rated head and neck cancer symptoms (EORTC QLQ-H&N35) and; QoL (EORTC QLQ-C30).

Study description

Background summary

Swallowing dysfunction and xerostomia are the most frequently reported radiation-induced side effects (RISE) after (chemo) radiation ((CH) RT) in head and neck cancer (HNC) patients and have a major impact on the general dimensions of quality of life (QoL). In radiation-oncology, normal tissue complication probability (NTCP) models based on dose-volume parameters are being used to determine the risk of acute and late RISE. NTCP models containing genetic determinants of radiosensitivity, such as single nucleotide polymorphisms (SNPs), may improve model performance and thus enable more individualized radiotherapy. Information of the predictive value of SNPs or SNP signatures among patients with HNC is currently not available.

Study objective

The main objective of this project will be to test the hypothesis that SNP profiles can improve the performance of predictive models for the most frequently reported late RISE, i.e. dysphagia, in HNC patients after curative (CH) RT. Secondary objectives will be improvement of NTCP models for HNC patients by adding SNP profiles predictive of (1) acute mucositis; (2) acute dysphagia; (3) salivary dysfunction; (4) acute xerostomia; (5) late xerostomia; (6) osteoradionecrosis; (7) hypothyroidism; (8) patient-rated HNC symptoms and; (9) quality of life.

Study design

Prospective non-randomized observational cohort study.

Study burden and risks

Since April 2007 all HNC patients are subjected to a standardized follow up program in which all endpoints are (prospectively) assessed on a routine basis and blood is routinely withdrawn every visit. From all these patients additional informed consent will be obtained for the purpose of genome wide SNP profiling. For the purpose of this project 10 ml EDTA blood of all HNC patients still alive will be obtained for DNA isolation to perform genome wide SNP association studies. DNA that is left after performing SNP profiling will be stored for validation studies and/or future research. In addition, 10 ml extra EDTA blood (plasma + buffy coat), 8.5 ml serum blood and a 2.5 ml RNA tube will be collected from the patients for the purpose of validation studies and/or further research. Informed consent from all patients will be obtained to store patient material for future (validation) studies. This SNP study will be linked to the SFP in patients with HNC. Patients will be recruited during the standard follow up visits at the department of Radiation Oncology. It is anticipated that all patients can be recruited within 12 months. Given the low extra burden for patients (four (extra) blood collection tubes) the accrual is expected to be high (approximately 90%). For most patients blood sample collection can be done simultaneously during blood sample collection for regular check for thyroid function or during the regular blood sample collection prior to radiotherapy, so no extra punctures are required. The samples will be stored in management of LifeLines.

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. Histological proven head and neck cancer;
2. Primary site in the oral cavity, oropharynx, hypopharynx, nasopharynx, paranasal sinuses, and/or salivary glands;
3. Treatment with curative intent with primary or postoperative radiotherapy either or not combined with systemic treatment;
4. Northern European ethnicity (ethnicity is a known confounder in SNP association studies);
5. Willing and able to comply with the study prescriptions;
6. 18 years or older;
7. No prior radiation (in the head and neck area);
8. Patients must have sufficient knowledge of the Dutch language to understand the meaning of the study as described in the patient information;
9. Have given written informed consent before patient registration.

Exclusion criteria

Prior radiotherapy.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-09-2013
Enrollment:	2000
Type:	Actual

Ethics review

Approved WMO Date:	18-06-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-08-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL37151.042.12