Late term complications after radiotherapy of the neck; Cognitive functioning and gait.

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To study late term complications after radiotherapy of the neck

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON36964

Source
ToetsingOnline

Brief title
Late term complications after radiotherapy of the neck

Condition

- Central nervous system vascular disorders

Synonym
Stroke, vascular injury

Research involving
Human

Sponsors and support

Primary sponsor: Neurologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Head and Neck cancer, Radiotherapy, Vasculopathy

Outcome measures

Primary outcome

Incidence, location and composition of extra- and intracranial postirradiation

vessel wall assessed by MRI/A and duplexultrasonography.

Secondary outcome

- Incidenc of white matter lesions, (silent) brain infarctions and atrophy,

assessed bij MRI/A

- Incidence cardio and cerebrovascular diseases

- Scores on balans and gaith parameters

- Incidence cognitive dysfunctioning, assessed by a neuropsychological

excamination

Study description

Background summary

Radiation induced carotid vasculopathy with subsequent increased risk of cerebrovascular accidents is a well known late complication of Radiotherapy (RT) of the neck. More knowledge of the underlying pathofysiology is needed to develop prevention strategies and to identify patients at risk. We have an unique prospective cohort of patients treated for head and neck malignancies with prior irradiation of the neck. Baseline and 2 years after RT Intima Media Thickness (IMT) measurements of both carotid arteries are performed. We will expand the follow up period of this cohort to 5 years after RT to answer the following questions.

The first question to be answered is what is the relation between RT and imaging characteristics of atherosclerosis? The hypothesis is that irradiation induces premature atherosclerosis. It is unclear whether the location and composition of these postirradiation vessel wall changes are different from

those in more common atherosclerosis due to cardiovascular risk factors. With advanced imaging techniques we will assess the extra- and intracranial arteries in all patients.

The second question to be answered is what is the relation between RT and asymptomatic cerebral vascular changes? It is known that the prevalence of silent brain infarcts is up to fivefold higher than the prevalence of stroke in the community. These changes have a major impact on cognitive functioning and gaith and balance disorders. Carotid artery pathology increases this risk. To assess this, all the study patients will undergo MRI of the brain to score white matter lesions, silent brain infarcts and cerebral atrophy.

The third question to be answered is what is the relation between RT and symptomatic vascular events? When carotid or cerebral arteries are within the RT field, there is an increased risk to develop cerebrovascular accidents. Within the first 2 years after RT of the neck, we found a 8 times higher incidence of stroke and a 16 times higher incidence of TIA, when compared to the community. Cerebrovascular risk factors and vascular diseases will be assessed in all patients.

The fourth question to be answered is what is the relation between RT induced cerebral vascular lesions and gaith disturbances? To assess this we will perform quantitative gaith analysis in all patients.

The fifth question to be answered is what is the relation between RT and cognitive functioning? We know that silent brain infarcts in the community are associated with worse cognitive ability and increased risk of developing dementia. Therefore, we will perform neuropsychological tests in all the study participants.

Study objective

To study late term complications after radiotherapy of the neck

Study design

Design: Prospective cohort study

All patients had already baseline (before RT) and 2 years after RT follow-up. At every visit they underwent a structured interview, neurological excamination, laboratory investigatuin ans duplex ultrasonography.

At the 6 year follow-up patient will undergo:
- Structured interview and neuroloical excamination, including ECG
- Fasting laboratory investigation (glucoses, cholesterol)
- MRI/A of brain and extra- and intracranial arteries

- Duplex Ultrasonography of carotid arteries (IMT, strain imaging)
- Gaith analysis
- Neuropsychological Excamination and questionaries (HADS, CIS)

Study burden and risks

When clinincal relevant abnormalities are found on the laboratory investigation, ECG, duplex ultrasonography or MRI/A, the studycoordinator will inform the patient and the general practicioner. All MRI/A's will be officially asessed by a neuro-radiologist.

Contacts

Public
Selecteer

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Scientific
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

RT of the neck because of a T1/T2 (N0M0) laryngeal carcinoma, T1/T2 (N0M0) parotid carcinoma / pleomorphic adenoma, T1/2 (N1/2M0) oro/hypopharynxcarcinoma or non-Hodgkin/Hodgkin lymphoma and a minimal follow-up of 6 years post RT.

Exclusion criteria

History of cerebrovascular disease, pregnancy or breast-feeding, ongoing treatment with an HMG-coA reductase or cytochroom P450 inhibitor, active liver disease or > 3 times the upper limit of serum transaminases, 5 times the normal level of creatine phosphokinase, serum cholesterol > 7 mmol/L and a life expectancy < 2 years. Contra-indication for (contrast enhanced) MRI/A.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2012
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO

Date:	23-08-2012
Application type:	First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL41008.091.12