

Long term vascular and psychosocial complications in adolescent and young adult survivors of head and neck cancer treated with radiotherapy.

Published: 25-11-2019

Last updated: 10-04-2024

Primary objective: To investigate in Adolescent and Young Adult (AYA) Head and Neck Cancer (HNC) survivors treated with unilateral radiotherapy 5-10 years before, the long-term vascular complications in terms of carotid wall changes (ultrasonography...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON48049

Source

ToetsingOnline

Brief title

Late Effects Head and Neck Cancer

Condition

- Cardiac disorders, signs and symptoms NEC
- Miscellaneous and site unspecified neoplasms benign
- Central nervous system vascular disorders

Synonym

Vascular toxicity

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Head and Neck Cancer, Late Effects, Radiotherapy, Survivor

Outcome measures

Primary outcome

1. Vascular complications:

- a. Intima Media thickness on ultrasonography in the irradiated versus the non-irradiated artery
- b. Carotid wall elastography on ultrasonography in the irradiated versus the non-irradiated artery
- c. Carotid wall thickness on MRI in the irradiated versus the non-irradiated artery
- d. Radiological characteristics of carotid wall changes on MRI of the irradiated versus the non-irradiated artery
- e. Cerebral infarctions and white matter lesions on MRI
- f. Cardiovascular risk profile 5-10 years after radiotherapy because of HNC

Secondary outcome

2. Psychosocial complications:

- a. Cognitive function 5-10 years after RT in HNC patients
- b. Frequency of memory complaints, anxiety, depression, fatigue

Study description

Background summary

With increasing numbers of cancer survivors, strategies to prevent long-term complications in cancer patients become more important. Adolescent and Young Adult (AYA) Head and Neck Cancer (HNC) survivors are prone to long-term complications, especially vascular and psychosocial complications. Although several studies point to the importance of these long-term complications, structured survivorship care for AYA HNC survivors is still lacking.

Study objective

Primary objective:

To investigate in Adolescent and Young Adult (AYA) Head and Neck Cancer (HNC) survivors treated with unilateral radiotherapy 5-10 years before, the long-term vascular complications in terms of carotid wall changes (ultrasonography, MRI), cerebral vascular complications ((silent)brain infarctions, white matter lesions) and Cardiovascular Risk profile.

Secondary objective:

To investigate in Adolescent and Young Adult (AYA) Head and Neck Cancer (HNC) survivors treated with unilateral radiotherapy 5-10 years before, the long-term psychosocial complications (subjective memory complaints, anxiety, depression, fatigue, experience of positive health, working disabilities, objective memory complaints).

Study design

Cross sectional cohort study.

Intervention

Structured survivorship care * 5 years after radiotherapy conform the Personalized Cancer Survivorship Care Model of the Radboudumc Expertisecenter of late effects after cancer, extended with carotid ultrasonography (IMT and elastography), MRI of the carotid arteries and brain), neuropsychological assessment battery and self-reported questionnaires concerning depression, fatigue, QoL, positive health and employment status.

Study burden and risks

The estimated time window per patiënt is:

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Questionnaires: 60 minutes
MRI: 30-60 minutes
Ultrasonography: 30 minutes
Neuro Psychological Examination: 60 minutes

The appointments will be planned at the same day as the regular appointment in the hospital.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Patients treated with unilateral radiotherapy of the neck at adolescent or young adult age (18-40 year) 5-10 years before.
- Competent to make own decisions

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- *18 years of age

Exclusion criteria

- Contra indication MRI
- Not able to understand the Dutch language

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): 22-01-2020

Enrollment: 40

Type: Actual

Ethics review

Approved WMO

Date: 25-11-2019

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 05-03-2020

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 21-07-2020

Application type: Amendment
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	NL71550.091.19