Using advanced MRI techniques to improve the planning treatment for head-neck hyperthermia and radiotherapy

Published: 05-03-2013
Last updated: 26-04-2024

The purpose of this study is to determine the thermal parameters by MRI scans at different time points during head-neck radiotherapy combined with hyperthermia treatment series.

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

Summary

ID

NL-OMON39761

Source
ToetsingOnline

Brief title
MRI techniques improving planning head-neck hyperthermia radiotherapy

Condition

- Other condition
- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Head-neck tumours

Health condition

Hoofd-hals tumoren

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-Neck tumours, MRI, Thermal parameters

Outcome measures

Primary outcome

• Ability to measure specific cooling in the tumour and normal tissue in the

head and neck region.

• Improved head and neck hyperthermia treatment planning by making use of a

patient-specific cooling.

• Mapping the need to adapt the course of combined radiotherapy and

hyperthermia treatment series treatment planning.

Secondary outcome

NA

Study description

Background summary

Advanced tumours in the head/neck region are usually treated with radiation therapy, possibly supplemented by chemotherapy. This treatment does not always lead to desired results and the side effects can be exhaustive. After treatment, patients often experience loss of saliva production and loss of swallowing function. For different types of tumours and different tumour sites, it has shown that hyperthermia the tissue temperature increases to 39-45 ° C, the effects of radiotherapy and chemotherapy markedly improved and barely contributes to the side effects. Until recently it was not possible to heat the head/neck region deeper than 4 cm below the skin. With the recent

development of the Hyper Collar now tumours can be heated deeper than 4 cm below the skin.

The Hyper Collar consists twelve antennas that can be independently controlled. Optimal use of this device requires a patient-specific treatment planning by using computer simulations.This process of treatment planning based on computer simulations, is analogous to the procedure for radiotherapy, wherein for each patient prior to the treatment planning such a treatment is made. On a Computed Tomography (CT) scan the target area and the critical normal tissues (spinal cord, brains, salivary glands) are visible and through a planning system the optimal dose can be calculated. For hyperthermia treatment planning the same CT will be used. However, the CT data deduce a a fully 3D patient model consisting of different tissue structures. To these tissue structures, allocated electromagnetic prope will be assigned. By the 3D model, the patient's energy dose for the hyperthermia treatment can be calculated and optimized.

The results of the present study (MEC 2010-318) show that the addition of an MRI scan, in addition to the normal CT scan, provides a rapid and accurate underwriting of the tissues in the head and neck region which the energy dose distribution can be accurately predicted. However, for a good prediction of the thermal dose, also detailed information about the cooling of the tissues is required. For the calculation of the thermal dose for the hyperthermia treatment planning, the thermal properties of the tissue is very important. In particular, the presence of blood vessels and the blood flow in the tissue are important, because the released heat removes through the blood and thereby it provides cooling of the tissue. In calculation of the actual thermal dose is assumed that the blood flow does not change from patient to patient. Furthermore, there also is a homogeneous tissue blood supply assumed. However, it is known that the blood flow in tissue is very heterogeneous, particular in tumours. For example, a blood vessel through the tumour ensures that carry heat away from the tumour, so that the temperature is much lower than expected and so suboptimal temperatures can be achieved in the tumour. To specify and accurate our thermal dose, it is important to map the vascular tree both as the perfusion by using advanced MRI techniques.

Because of the combined radiotherapy and hyperthermia treatment the tumour changes during the treatment series. This indicates changes in the characteristics of the tumour, but also in the tissues surrounded region. It is possible that the beginning of the treatment planning is no longer accurate at the end of the treatment series. This means that the patient characteristics may have to adjust to an accurate treatment for a maximal therapeutic effect. To make the change for mapping the properties, we want three times during the treatment series (assuming 35x2Gy, 6x/week diagram).

This information, makes it possible to use the blood flow in the tumour and the surrounding tissue, that can be determined for each patient. Furthermore, with the date we can determine whether blood flow during combined hyperthermia and radiotherapy treatment series changes. With this information we can decide whether it is necessary to adapt hyperthermia and radiotherapy treatment planning during the treatment series.

Study objective

The purpose of this study is to determine the thermal parameters by MRI scans at different time points during head-neck radiotherapy combined with hyperthermia treatment series.

Study design

The first MRI scan will preferably be scheduled on the same day as the planning CT, which is the standard specification for radiotherapy treatment planning. The 2nd and 3rd MRI scan will be respectively in the 2nd week and in the 5th week of the treatment series (assuming 35x2Gy, 6x/week schedule) are planned. These MRI scans will always be planned adjacent to radiotherapy and / or hyperthermia treatment.

Study burden and risks

The MRI scan is harmless to health. The MRI scanner consists a strong magnet. This means that some people are not allowed in the MRI scanner, namely people with pacemakers, with some shunts with metal in their bodies. Prior to the MRI the physician there will be a questionnaire to check whether it is safe to undergo the MRI scan. Allergic reactions to the contrast are very rare, but can not be administered in a poor kidney function.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

informed consent
minimal age of 18
tumour in head-neck area indicated to irradiation i.c.w. hyperthermia
patient must be able to lie still for long enough (approximately 45 minutes)

Exclusion criteria

no informed consent
claustrophobia
contra-indication to MRI research
contra-indiation to MRI contrast
pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2012
Enrollment:	24
Type:	Anticipated

Ethics review

Approved WMO

Date:	05-03-2013
Application type:	First submission
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	NL42050.078.12