Optimization of MRI scan protocols for radiotherapy and hyperthermia treatment planning

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The main goal of this study is to obtain MRI scans for investigating new algorithms for improvement and acceleration of patient model generation for radiotherapy and hyperthermia treatment planning.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON34126

Source
ToetsingOnline

Brief title
Hyper MRI

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
cancer of the head and neck

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: Hyperthermia, MRI scan protocols, Optimalisation, radiotherapy

Outcome measures

Primary outcome

- Speed and accuracy of segmentation algorithms based on MRI scans.

Secondary outcome

- Influence of positioning on segmentation results (anatomical position vs

radiotherapy position).

Study description

Background summary

Advanced tumors in the head and neck region are normally treated with radiotherapy, sometimes with the addition of chemotherapy. This treatment is not always successful and side-effects are severe. After treatment, patients suffer from losing saliva production and swallowing functionality. Hyperthermia, rising tissue temperature to 39-45°C, has shown to improve radiotherapy and chemotherapy for various tumors and different tumor-sites while the increase in side effects is negligible. With the recently developed HYPERcollar, heating in the head and neck region deeper than 4cm from the skin became possible.

The HYPERcollar, consists of a circular array of twelve antennas with independent control. Optimum use of this arrangement requires patient-specific treatment planning based on detailed computer simulations. Such simulations require a full 3D tissue distribution in which about 15 different tissues are distinguished. At this moment, computed tomography (CT) scans are used for generating this patient model.

CT scans, however, fail to show tissue transitions between soft-tissues that are highly relevant for electromagnetic simulations. Magnetic resonance imaging (MRI) is a safe, reproducible, non-invasive, technique that can be used to show human tissue, with a focus on soft-tissue interfaces.

To investigate if creating 3D patient models can be improved and accelerated by using both CT and MRI data we need to obtain such data from patients. This is

important because tissue distributions can be influenced severely depending on size and location of the tumor. Further, we need to assess if the MRI must be taken in radiotherapy position (with head support and mask) or in the, more comfortable, anatomic position suffices.

Study objective

The main goal of this study is to obtain MRI scans for investigating new algorithms for improvement and acceleration of patient model generation for radiotherapy and hyperthermia treatment planning.

Study design

Patients eligible for radiotherapy treatment of a tumor in the head and neck region are selected. After informed consent, patients will receive two MRI scans in addition to their CT for radiotherapy treatment planning. The two MRI scans with the patient in two different positions are required to investigate the influence of variations on the outcome and robustness of the segmentation algorithms.

Study burden and risks

With the screening for contraindications, no objective risks are inherent to the use of the MRI and contrast.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

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

's Gravendijkwal 230
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;
age over 18 years;
Tumor in the head-neck region that requiers radiation;
Able to lay still for a prolonged time (about an hour);

Exclusion criteria

No informed consent;
Contra-indications for MRI (incl. Claustrophobia, metal implants, renal insufficiency, pacemaker etc.);
Contra-indications voor MRI-contrast;
pregnancy;

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting

Start date (anticipated):	01-12-2010
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	16-11-2010
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	NL33826.078.10