Deep learning based MR Only Radiotherapy for head-and-neck cancer

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28332

Source
Nationaal Trial Register

Brief title
Deep MR Only RT

Health condition

head-and-neck cancer

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: EIT Health

Intervention

Outcome measures

Primary outcome

the percentage of patients in the validation cohort for which the dosimetrical accuracy is within tolerance for at least 80% of the organs and targets when the synthetic CT is used for dose calculations.

Secondary outcome

the percentage of patients in the validation cohort that meet for 80% of the organs the criteria for contouring accuracy, namely that 80% of the contour points need to be within 2 mm from the gold standard contours.

Study description

Background summary

Rationale: In the Netherlands about 3000 patients are diagnosed with head-and-neck cancer each year of which the majority is treated with (chemo)-radiotherapy. As part of the preparation of the radiotherapy treatment, both a CT scan and a MRI scan are acquired of the patient in treatment position. The MRI scan is acquired to clearly depict and delineate the tumor while the CT scan is necessary to plan the radiotherapy treatment beams. The current preparation procedure has a couple of disadvantages. First, two patient appointments are required for the CT and MRI scan. Second due to unavoidable slight variations in patient position at the time of the CT and MRI, both scans need to be registered. Any misalignment in registration is at the expense of the treatment accuracy. Third, delineation of the organs at risk is a tedious manual process that can takes hours per patient.

Within a European consortium funded by EIT Health we are developing a special type of MRI sequence that can be used to create a synthetic CT scan. We hypothesize that using this synthetic CT it will no longer be necessary to acquire a separate CT, avoiding the problems stated above. Moreover the consortium develops automated tools for contouring based on deep learning that could be used to automatically delineate organs at risk, possibly saving considerable preparation time.

Objective: Primary objective: to acquire patient data required to optimize/train a method to generate synthetic CT scans from MRI scans and to determine the suitability of the synthetic CT scans for radiotherapy treatment planning.

Secondary objective: To evaluate if the deep learning based autocontouring can lead to delineations of organs at risk comparable to those delineated by an expert radiation-oncologist.

Study design: Technical feasibility study
Study population: 60 Patients (age >18 yr) with head-and-neck cancer scheduled for primary (chemo-)radiotherapy where a planning MRI is performed as part of standard work up.
Intervention (if applicable): The MRI scanning time of the clinical work is 20 minutes and will be extended for the purpose of this study by 15 minutes.

Main study parameters/endpoints: Primary: the percentage of patients in the validation cohort for which the dosimetrical accuracy is within tolerance for at least 80% of the organs and targets when the synthetic CT is used for dose calculations.

Secondary: the percentage of patients in the validation cohort that meet for 80% of the

organs the criteria for contouring accuracy, namely that 80% of the contour points need to be within 2 mm from the gold standard contours.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The burden consists of a 15 minutes longer MRI scan time than used in standard workup: 35 minutes instead of 20 minutes scan time. During the scanning, the patients wear the radiotherapy immobilization mask required for the clinical scans. There are no risks associated with the intervention. The study does not affect the treatment.

Study objective

The obtained MR sequences can be converted into syntehetic CT scans that are suitable for accurate radiotherapy treatment planning.

Study design

Pre-treatment

Contacts

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Eligibility criteria

Inclusion criteria

60 Patients (age >18 yr) with head-and-neck cancer scheduled for primary (chemo-)radiotherapy where a planning MRI is performed as part of standard work up.

Exclusion criteria

Having any physical or mental status that interferes with the informed consent procedure.
Contraindications for MRI (e.g. claustrophobia, arterial clips in central nervous system)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-11-2019
Application type:	First submission

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
NTR-new	NL8167
Other	METC Erasmus MC : MEC-2019-0805

Study results