Improvement of reproducibility during radiation treatment in Head and Neck cancer patients

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Ethical review	Not approved
Status	Will not start
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON44508

Source
ToetsingOnline

Brief title
Improvement reproducibility in H&N cancer radiotherapy

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Head and Neck cancer, Throat cancer

Research involving
Human

Sponsors and support

Primary sponsor: Haaglanden Medisch Centrum
Source(s) of monetary or material Support: het wetenschapsfonds van het HMC betaald

de helft van de kosten van de hoofdsteunen

Intervention

Keyword: Head and Neck cancer, Radiation Treatment, Reproducibility, Toxicity

Outcome measures

Primary outcome

Translations and rotation measured in each patient on the images before and

after the radiation treatment.

Secondary outcome

Not applicable

Study description

Background summary

At the radiation therapy department of the Haaglanden Medical Center (HMC) Antoniushove, approximately 1,700 patients are irradiated annually, with an average of 60 patients being treated in the Head and Neck area (H&N).

A benchmark survey had been performed between the radiation therapy departments in the Netherlands in 2016, demonstrating that the radiation therapy technique for the H&N patient group of the HMC Antoniushove needs to be improved. The department started to optimize the H&N radiation technology in May 2017. The plan is to start with a Volumetric Arc Therapy (VMAT) irradiation technique from October 2017. This means that with the same dose in the target area, the critical organs will be avoided as much as possible with a faster treatment time. The aim is to reduce the toxicity of the treatment.

In addition, since April 2017, HMC has used another method of position verification in the H&N area, the so-called ConeBeamCT (CBCT). As a result of this improved imaging procedure (*matching* procedure), the radiation therapists can perform the *match* more accurately. Also, the target area by the attending radiation oncologist can be checked daily for changes by comparing it with the planning CT. Finally, the HMC will use a table to correct for rotations in the patient position and in doing so optimize the radiation treatment. With these new methods, multiple CBCT*s are made to monitor this accurately during the radiation treatment.

By changing the radiation technique, the reproducibility of the location of the H&N patients is even more important because the 95% isodoseline at VMAT is encompassing the target area more closely. Adding an individual headrest could improve the reproducibility of the patient's position. Another gain is that, due to better reproducibility, the margin of the target area can be reduced from 5 to 3mm. And thus the risk of toxicity might further decrease.

Study objective

Currently, a 5-point mask and a standard headrest is used in the H&N patients. By replacing the standard headrest for an individual headrest that includes both the head, neck and part of the shoulders, it is expected that the translations and rotations will be reduced because the patient is more firmly fixed compared to the standard headrest. With the benefit that the radiation oncologist can maintain smaller margins around the target area, thus saving more healthy tissue. The individual headrest CBCT*s are evaluated both with and without the rotation of the rotation table. In order to make clear what profit the individual headrest adds to the standard headrest and the use of the rotation table.

Study design

To find out what the benefits of the different applications are, four different groups of patients are compared. The use of the individual headrest as well as the addition of the rotary table are distinguished.

The acquired data with the new patient positioning technique is used to compare the data obtained with the addition of the individual headrest.

Four groups of 10 patients are distinguished in this study:
1. Standard headrest without rotary table
2. Standard headrest with rotary table
3. Individual headrest without rotary table (after approval METC)
4. Individual headrest with rotary table (after approval METC)

In this way, a distinction can be made between the added value of the individual headrest and the added value of the rotary table.

The type of individual headrest was determined by the research team after testing various types of headrests in healthy volunteers (working in the HMC radiotherapy department) advised by a team of two RTTs and two technicians. The headrest of the Klarity R550-T has been selected. The costs of these headrests are funded by the firm and the HMC.

In the HMC, we work with an on-line correction method in which we correct for positioning inaccuracies on a daily bases for each individual patient. The

positioning differences are determined by using CBCTs. In the radiotherapy, the positioning inaccuracies are analyzed according to the method of "van Herk et al.".

In the described analysis, day-to-day variations (interfraction) are analyzed after patient position correction for the four different situations. In addition, the intrafractional variations are calculated (difference in position before and immediately after irradiation).

The translations and rotations we find in each patient are collected and count for the entire group. Based on the collected data, the vector, the mean translation and rotation can be determined between the different fractions. In Excel, this data is processed and displayed. Eventually, the results of the four different groups described above, are compared.

In order to be able to measure the patient's inter- and intrafractional variation, CBCTs are made before irradiation and after irradiation, according to the current protocols. This method is used by default when introducing new techniques. Which profit in accuracy can be achieved with the addition of the rotary table will be measured as well.

The CBCT is made with a pre-set that meets the requirements to detect changes in tumor volume according to the current protocol. The pre-sets of the CBCT in the HMC are adjusted to minimize the dose in the patient.

In the software program, the 'match' will be performed with a predetermined clip box, which will be executed according to the current protocol. In addition, the displacement in the shoulder area will also be registered. This will be done using a 'mask', which will be placed at a representative point. This 'mask' image processing takes place after the treatment.

Intervention

Making of an individual headrest of the head and the shoulders.

Study burden and risks

An individual headrest will be made on the day of the CT scan, this will take ten minutes extra on the day of the CT scan.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Head and Neck (H&N) cancer
Curative treatment
Use of 5 point H&N mask
Written informed consent
Older than 18

Exclusion criteria

Palliative Head and Neck cancer treatment
Patient is pregnant
Patients not able to understand the Ducth language
No written informed consent available

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

Date:	06-11-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL63345.098.17