The effect of individualized fixation devices on the actual given dose in patients treated with curative (chemo)-radiation for head and neck cancer: a pilot study

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Primary objectiveThe objective of this pilot study is to test the hypothesis that the use of individual head supports will result in an actual given dose to both the target volumes as well as organs at risk that corresponds better to the planned...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34090

Source
ToetsingOnline

Brief title
MASK-Trial

Condition

- Other condition

Synonym
head and neck cancer

Health condition

hoofd-hals tumoren

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dose distribution, Head and neck cancer, head supports

Outcome measures

Primary outcome

The primary endpoint of this study is the actual given dose. The actual given dose is the dose administered to the patient during treatment, taking into account patient positioning accuracy and patient deformations. This actual given dose will in general deviate from the planned dose that was calculated based on the planning CT only. The actual given dose for the two different groups will be calculated and compared to the planned dose. The dose distributions of the following structures will be taken into account:

- Gross Tumour Volumes (GTVprimary tumour and GTVlymph node metastases)

- Clinical Target Volumes (CTV70 and CTV54.5)

- Planning Target Volumes (PTV70 and PTV54.5)

- Spinal cord

- Parotid glands (ipsilateral and contralateral)

- Submandibular glands (ipsilateral and contralateral)

- Pharyngeal constrictor muscles (superior, medium and inferior)

- Thyroid gland

Secondary outcome

The first secondary endpoint is dose calculations on CBCT data.

A more sophisticated and efficient method to calculate the actual given dose from the CBCT scans will be developed. The CBCT images are acquired on the treatment table of the linac, just before start of treatment. Therefore, dose calculations based on the CBCT images correspond better with the actual dose distribution than calculations based on repeated CT scans. However, at the moment the dose calculations based on CBCT scans are not as accurate as those based on conventional CT scans. This is caused by the different imaging technique that is used for CBCT*s resulting in less image quality than a conventional CT. Using Deformable Image Registration (DIR) techniques will make it possible to deform the planning CT to obtain new CT images with the anatomical information of the CBCT scan and the image quality of a conventional CT. The results obtained with this method will be validated with the results obtained from the repeated CT-scans.

The second secondary endpoint is the positioning accuracy.

In head and neck patients, a curative treatment course generally consists of 35 treatment fractions in 6 to 7 weeks. The current procedure is to make CBCTs on the first 4 treatment fractions and subsequently weekly. Based on the findings

of these images, inaccuracies are calculated in terms of standard deviations and standard errors and translated into positions corrections according to a standardised protocol. The following endpoints regarding repositioning accuracies will be assessed:

- Translations (cranial-caudal, posterior-anterior and left-right)

- Rotations (Roll, yaw and pitch)

For the purpose of this study, position accuracies will be calculated for both groups. This is part of the current standard procedure and does not require extra patient burden.

Study description

Background summary

Radiotherapy plays a pivotal role in the treatment of head and neck cancer, either as single modality or as part of a multimodality approach combined with surgery and/or systemic treatment like chemotherapy or cetuximab.
Modern radiation delivery techniques enable increasing possibilities to administer a high dose to the target volume (including the tumour) while organs at risk (OARs) can be increasingly spared. These highly conformal techniques require an accurate delineation of 3D target volumes and OARs on the planning CT scan made prior to treatment. Based on this planning-CT, radiotherapy treatment planning is carried out. Higher conformity of dose distributions to the target volumes requires increasing quality assurance of patient positioning during the course of treatment as tighter dose distributions around the target increases the risk of geometric misses during treatment in case of relatively small deviations. Therefore, all patients with high conformal techniques, such as intensity modulated radiotherapy (IMRT) which is the current standard at our department for head and neck cancer irradiation, are subjected to well defined position verification and repositioning protocols during the entire course of treatment. These protocols are aiming to ensure as much as possible that the planned radiation dose as assessed on the planning-CT scan are actually given to the patient during the entire course of treatment (actual given dose).
Deviations of the actual given dose with respect to the planned dose may result from different sources, including:
- Translations (cranial caudal, anterior posterior and lateral directions):

these deviations can be compensated by repositioning during treatment by the currently used position verification and repositioning protocol;
- Anatomical changes due to tumour shrinkage, radiation-induced swelling and/or weight loss. These changes can only be accounted for by re-planning (adaptive radiotherapy);
- Rotations, defined as deviation of the angle between the head and neck: these deviation cannot be corrected by repositioning, as correction of the head-part of the target volume will result in deviation of the neck-part and vice versa. Rotations could possibly be prevented by using other fixation devices, which will be the subject of this study.

For patients with tumours in the head and neck area fixation devices are used during treatment to obtain a fixed and reproducible position of the head and neck on the treatment table. The current fixation devices consist of an individual thermoplastic mask in combination with a standard head support. Results obtained by others indicate that using individual head supports instead of standard head supports improve the positioning accuracy, in particular of rotations between the neck and head, which cannot be corrected for by repositioning of the patient. However, the effect of individual head supports on the actual given dose has not been investigated yet.

The use of individual head supports is more expensive and more time-consuming than the use of standard head supports. From this point of view, it is worthwhile to investigate if and to what extend the individual head supports will improve the actual given dose as this will be the most clinically relevant outcome parameter.

Study objective

Primary objective
The objective of this pilot study is to test the hypothesis that the use of individual head supports will result in an actual given dose to both the target volumes as well as organs at risk that corresponds better to the planned dose than with the currently used standard head supports.

Secondary objectives:
The secondary objectives are:
- Develop a method to calculate the actual given dose based on the CBCT scans acquired on the treatment table of the linac, just before start of treatment.
- To compare reposition accuracies between the individual head support and the standard head support.

Study design

This is a pilot study (feasibility study) to determine the difference between the actual given dose with the two different head supports.

Patients that participate in this study will be treated will receive both head supports and a planning-CT will be made with both supports. A treatment plan will be made on both planning-CTs. The patients will, however, only be treated with the individual head support. In weeks 1, 3, 5 and the last week of treatment repeated-CTs will be made with both head supports.

During the treatment cone-beam CT (CBCT) scans will be used for position verification. The CBCTs will also be made with both head supports. This means that 10 extra CBCT images will be made for patients that participate in this study.

Study burden and risks

If the patient decides to participate in this study he/she will have the advantage to be treated with the individual head support, whereas the patients that do not participate in this study will be treated on the standard head support. The individual head support is more comfortable and is expected to give better positioning of the patient. For this study, the patient will have to spend some extra time on the department, due to the extra CT- and CBCT-scans, but he/she will not have any additional visits to the department as these investigations can be carried out in directly following there daily visits to the department. The additional dose of these extra CT- and CBCT-scans is 129.5 mSv. This extra radiation dose exposure is considered acceptable (0.20%) in relation to the prescribed radiation dose (66.000-70.000 mSv). Prior to the start of the study, the protocol has to be approved by the medical ethics review committee. Approval will be indicated in writing with reference to the final protocol number and date.

Contacts

Public
Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Postbus 30001
9700 RB Groningen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Intended curative primary or postoperative radiotherapy for cancer of the head and neck, either or not combined with systemic treatment (chemotherapy or cetuximab);
- Suitable for treatment on LINAC E (with cone beam CT);
- Age >18 years;
- WHO performance status 0-2;
- Women of childbearing potential must not be pregnant or lactating;
- Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial;

Exclusion criteria

Patients with postoperative wound healing problems

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-08-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	10-08-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL32387.042.10