Prone versus supine positioning for rectal cancer irradiation using volumetric modulated arc therapy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational invasive

Summary

ID

NL-OMON48025

Source
ToetsingOnline

Brief title
VMAT prone vs. supine

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
adenocarcinoma of the rectum, Rectal cancer

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Positioning, Radiotherapy, Rectal cancer, VMAT

Outcome measures

Primary outcome

The dosimetric indices of all 40 patients will be statistically analyzed using a patient-averaged dose-volume histogram, to evaluate the advantages and disadvantages in PTV coverage and OARs sparing for the prone and supine position.

Secondary outcome

Subgroup analyses of the dosimetric indices will be performed according to gender and radiotherapy course.

Study description

Background summary

Neoadjuvant radiotherapy has an important role in the treatment of rectal cancer patients, leading to a significant decrease in local recurrence rate. Conventionally patients are treated with a 3-beam 3D conformal radiotherapy (3D-CRT) technique, combining two lateral opposed fields with a posterior field. In the past decade advanced irradiation techniques such as volumetric modulated arc therapy (VMAT) have been developed. This is a new intensity-modulated radiation therapy treatment technique employing single or multiple radiation beams that rotate around the patient, resulting into highly conformal dose distributions in the target volumes, better sparing of organs at risk (OARs) and faster treatments.

The most important OARs in rectal cancer irradiation are the small bowel and colon (i.e. bowel bag), in which acute radiation enteritis, chronic diarrhea, and less frequent bowel stricture, perforation and hemorrhage can be caused. Multiple studies have shown a relationship between the dose to the bowel bag and the incidence of intestinal toxicity. VMAT substantially reduces high-grade acute and late toxicity compared to 3D-CRT.

Since January 2018 VMAT is available for rectal cancer patients at the Department of Radiotherapy in the Radboud University Medical Centre, with approximately 70 patients treated per year. With the use of 3D-CRT patients were irradiated in prone position, using a belly board and full bladder protocol, in order to reduce the amount of small bowel in the high dose region by pushing the bowel bag away from the target volume. However, in comparison with supine positioning, the combination of prone positioning and a belly board is known for less setup reproducibility and possible patient discomfort. Using highly conformal VMAT, prone positioning with the use of a belly board may no longer be superior to supine positioning when it comes to bowel bag dose. Only few studies have described the role of patient positioning in VMAT for rectal cancer, though including a relatively small number of patients, with conflicting results

Concluding from the above mentioned items, we assume that:
* Rectal cancer irradiation with VMAT results into highly conformal dose distributions and reduced intestinal toxicity, compared to conventional 3D-CRT.
* In terms of setup reproducibility and patient comfort, supine positioning is superior to prone positioning using a belly board.

We hypothesize that:
1. Using VMAT, the combination of prone positioning and a belly board may no longer be superior compared to supine positioning in terms of OARs sparing.
2. Optimal patient positioning may be different for male and female patients due to variations in pelvic anatomy.

Study objective

The primary aim of the study is to investigate the effect of patient positioning on OARs sparing in rectal cancer patients treated with VMAT (hypothesis 1).

The secondary aim of the study is to investigate the possible differences in optimal patient positioning for male and female patients (hypothesis 2).

Study design

* All patients will receive 1 extra planning-CT scan in supine position, alongside the standard planning-CT scan performed in prone position using a belly board. No intravenous, oral or rectal contrast will be used
* Delineation of target volumes (CTV, PTV) and organs at risk (bowel bag, bladder, femoral heads) on both CT scans
* For each CT scan a VMAT-treatment plan will be created
* For each patient treatment plans will be dosimetrically compared
* All patients will be irradiated in prone position using a belly board, according to current treatment protocol.

Study burden and risks

In conclusion, all patients will be asked to undergo 1 extra planning-CT scan compared to standard protocol. As a result of this scan, they will receive an additional mean effective dose of 10 mSv. In theory this extra CT scan may contribute to radiation-induced carcinogenesis, although the increased risk is estimated to be negligible compared to radiotherapy dose. By way of comparison, the average background radiation in the Netherlands is 2,5 mSv per year. No extra hospital visits or invasive treatments will be necessary. All planning scans will be performed in one session.

All patients will be irradiated in prone position using a belly board. In this way, treatment is similar to those of non-participating patients.

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

- Patients with rectal cancer indicated to receive neoadjuvant (chemo)radiotherapy
- Age >18 years
- Written informed consent

Exclusion criteria

- Patients unable to lie in prone position (e.g. due to stoma)
- Previous surgery or radiotherapy in the pelvic area

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2019
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	16-10-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-03-2020

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL68696.091.19