Treatment planning techniques in pelvic irradiated patients
Comparison between 3D conformal and IMRT treatment planning techniques in supine and prone position in patients who receive pelvic irradiation

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Primary objectives: To compare the dose volume histograms (DVHs) of the planning target volume (PTV) in prone and supine position, with 3D conformal and intensity-modulated radiotherapy (IMRT) planning in patients who receive pelvic irradiation To...

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

Summary

ID

NL-OMON34454

Source
ToetsingOnline

Brief title
IMRT in pelvic tumors

Condition

- Miscellaneous and site unspecified neoplasms benign
- Obstetric and gynaecological therapeutic procedures

Synonym
pelvic tumors

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 3-D conformal radiotherapy, IMRT, pelvic tumors, small bowel toxicity

Outcome measures

Primary outcome

* Coverage of the PTV

* Dmean of the small bowel (mean dose in the small bowel)

* V15 and V45 of the small bowel (volume of the small bowel which receives

respectively 15 and 45Gy)

Secondary outcome

* Dmean of the bladder, kidneys, sigmoid and, in case of gynaecologic patients,

rectal wall

* V25, V30, V35, V40 and V50 of the small bowel (volume which receives

respectively 25, 30, 35, 40 and 50 Gy)

Study description

Background summary

The aim of this study is to determine if in patients who are referred for pelvic irradiation, IMRT planning in comparison with 3-D conformal radiotherapy planning, gives the lowest dose to the small bowel without increasing the dose in other organs at risk (bladder, kidneys, rectum and sigmoid). In addition, we

want to determine in which patients (postoperative endometrial and/or cervical and/or rectal cancer patients), according to dose volume histograms, irradiation in prone position is superior to supine position. For this, we need to perform two consecutive CT-scans in prone and supine position respectively, and delineate on both scans the target organs as well as the organs at risk. Finally, we need to make four treatment plans for every patient, one IMRT plan in supine position, one IMRT plan in prone position, one 3D conformal plan in supine position and one 3D conformal plan in prone position and compare these plans with each other.

Study objective

Primary objectives:
To compare the dose volume histograms (DVHs) of the planning target volume (PTV) in prone and supine position, with 3D conformal and intensity-modulated radiotherapy (IMRT) planning in patients who receive pelvic irradiation
To compare the dose volume histograms (DVHs) in the organs at risk in prone and supine position, with 3D conformal and intensity-modulated radiotherapy (IMRT) planning in patients who receive pelvic irradiation

Secondary objectives:
To determine if and for which patients (postoperative endometrial and/or cervical and/or rectal cancer patients) IMRT is superior to 3D conformal planning
To determine if and for which patients prone position is superior to supine position

Study design

Patients, referred to our department for curative treatment of their gynaecological or rectum tumor, will be asked informed consent.
1 extra ctscan in supine position will be made in preparation for radiotherapy treatment. The target volume and critical organs will be delineated by the investigator on the routinely made ctscan and the additional ctscan . Radiation technologists will make 4 treatment plannings using 3-D conformal radiotherapy and IMRT in supine and prone position.

Intervention

No intervention

Study burden and risks

The extent of the burden for this patient group participating the study is very minimal. The additional ctscan takes only 5-10 minutes more and will give a dose of 4 Milliesievert. The risk of tumor induction is very low especially in comparison with the radiation dose the patient will receive. For the study patients there will be no benefit.
The IMRT planning might be benefitial with relation to the critical organs, especially the small bowels. Acute and long term toxicity will be less.
This will be benefitial for all patients that will be irradiated for a pelvic tumor.

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 who are referred to our Radiotherapy department for pelvic irradiation for a

gynaecological or rectal malignancy
* patients should be able to lie in prone position on a belly-board

Exclusion criteria

* unable to lie on a belly-board
* allergic to iv-contrast
* kidney failure (calculated GFR < 60ml/min)
* need for irradiation of the para-aortic lymph nodes

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2010
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL33187.018.10