Repeated CT study in patients with cervical cancer to assess organ motion for adaptive radiotherapy and proton therapy planning

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To develop a strategy for online-adaptive radiotherapy with protons in patients with cervical cancer.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON42122

Source
ToetsingOnline

Brief title
Repeat-CT study

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cervical cancer, cervical carcinoma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cervical cancer, CT scan, Proton therapy, Radiotherapy planning

Outcome measures

Primary outcome

A strategy for adaptive proton radiotherapy to irradiate patients with a

cervical carcinoma with protons in an accurate and safe way.

Secondary outcome

Developed and tested use of a plan library

The amount of robustness in treatment planning still necessary

Study description

Background summary

At this moment, photon irradiation is the standard of radiotherapy treatment in the Netherlands. Photon irradiation in patients with cervical cancer is accompanied by substantial acute and late side effects. A new approach to pelvic radiotherapy is proton irradiation. Due to the physical properties of protons, it can be expected that proton therapy will offer improved sparing of organs at risk compared with the state-of-the-art photon therapy. Hereby, toxicity during and after radiotherapy can be reduced.
In previous studies it has been shown that the pelvic target volume in cervical cancer has complex shapes and can be subject to large interfraction deformations due to changes in bladder and rectum filling and changes in tumor volume.
Since dose distributions in proton therapy are much more sensitive to anatomical variations than in photon therapy, it is necessary to find a strategy to account for these uncertainties. A promising approach is the use of plan libraries. In this method a pretreatment generated plan library based on a full and empty bladder CT-scan is used. Before each proton therapy treatment fraction a CT-scan will be acquired, in which the target and organs at risk will be segmented automatically. Based on the contour sets obtained the best fitting treatment plan will be selected out of the plan library. Next the selected treatment plan will be adapted to the observed variations in density along the proton beam paths.

In this study we want to develop this abovementioned strategy.

Study objective

To develop a strategy for online-adaptive radiotherapy with protons in patients with cervical cancer.

Study design

Patients will undergo two CT-planning scans, one with full and one with empty bladder as used in standard practice, which will be used for regular treatment planning. These scans will also be used to generate a plan library for this study. Four additional repeated CT-scans will be made for the study; these additional scans will be made about once a week during the treatment period and will be used to document the interfraction deformation and position of the target volume during treatment due to changes in filling of bladder and rectum, and changes in tumor volume due to tumor regression. Furthermore, these scans will be used to test the accuracy of the pretreatment generated plan library and to determine the amount of robustness that is still needed in treatment planning to compensate for residual uncertainties.

Study burden and risks

Participation in this study will cost patients 15 minutes per extra CT-scan made, so 60 minutes for the whole study. The additional radiation exposure due to the repeated CT-scans will be negligible compared to the radiation dose delivered by the radiotherapy. The estimated absorbed dose of a pelvic CT-scan at our CT-scanner is about 10 mGy. Therefore the additional radiation dose for this study will be about 4x10 mGy=40 mGy, which is about 0.09% of the total dose received.
Since patients will be treated with the standard photon therapy, there are no benefits to participating in this study, other than contributing to the improvement of the treatment for patients in the future.

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 histologically proven cervical carcinoma
Radiotherapy as primary treatment, with or without concurrent chemotherapy
FIGO stage I, II, III
>=23 fractions of radiation therapy planned (curative schedule)
Age >=18 years
Written informed consent

Exclusion criteria

FIGO stage IV

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):	14-04-2015
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)
Approved WMO Date:	27-10-2015
Application type:	Amendment
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL52017.058.15