Towards Adaptive Radiotherapy (ART) for Cervical Cancer:
CT-study of the effect of full and empty bladder on the position of the uterus

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Goal: Towards implementation of ART in women with cervical cancer to increase RT precision and reduce the risk of late radiation complications.Study question: What is the effect of bladder filling on the position of the uterus and tumour in women...

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

Summary

ID

NL-OMON47258

Source
ToetsingOnline

Brief title
Bladder filling and uterus position for ART

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cervical cancer, CT-scan, position verification, radiotherapy

Outcome measures

Primary outcome

Variability of uterus position under influence of filling of the urinary

bladder.

Secondary outcome

Daily variation in bladder filling (with cone-beam CT), tumorlokalization (with

fiducial gold markers), and tumour response (weekly MRI-scans).

Study description

Background summary

Radiotherapy (RT) combined with chemotherapy is the first choice of treatment in women with inoperable cervical cancer. The position of the uterus has a daily variation, which is particularly dependent from the amount of bladder filling. Therefore, patients customly are instructed to have a full bladder during radiotherapy. Despite this instruction, the bladder filling shows considerable daily variation, and thus also the position of the uterus and tumor. The position of the bladder can daily be visualized on the linear accelerator by a Cone-Beam CT-scan (CBCT), but the quality of CBCT is mostly not good enough to distinguish the uterus and tumour. Uterus and tumour can little better visualized on a conventional radiotherapy treatment planning CT-scan. Non-invasive gold standard for visualizing the tumour nowadays is T2-weighted MRI.
The present standard of care is to make just one RT treatment plan based on just one plannings-CT-scan. To account for daily position variation, the radiation oncologists takes a wide margin around the uterus.
However, if we would make more RT treatment plans in advance, based on CT-scans with a full and with an empty bladder, one could daily choose a more appropriate plan adapted to bladder filling as daily assessed by CBCT: Adaptive Radiotherapy (ART). Next, thanks to ART, future margins around the uterus could be reduced, thereby improving the precision of radiotherapy and reducing the

risk of late radiation complications.

Study objective

Goal: Towards implementation of ART in women with cervical cancer to increase RT precision and reduce the risk of late radiation complications.

Study question: What is the effect of bladder filling on the position of the uterus and tumour in women who have radiotherapy for cervical cancer?

Study design

Prospective cohort study

Study burden and risks

Nature and extent of the burden:
(1) Three Visicoil* fiducial 3 mm gold-markers will be placed in the cervix uteri, preferably during the standard investigation under anesthesia, or as an out-patient clinic procedure.
(2) The extra CT-scan with empty bladder will take 15 minutes extra plus a reduced dose (70 ml) standard iodine intravenous contrast agent. The extra CT-scan gives minimal extra radiation burden (15 mSv) compared to the subsequent radiotherapy (80.000 mSv).
(3) Five cone-beam CT scans will be made on the on the linear accelerator during the first week of radiotherapy; the extra dose (25 mSv) will be subrtracted from the daily radiation dose,
(4) Each week, a T2 weighted MRI will be made without i.v. contrast (20 min per scan; no radiation burden; 5 scans).

Gain for the patient:
(1) The use of fiducial gold markers may allow a better tumor localization and patient position verification on cone-beam CT,
(2) A minor advantage of lowering the radiation dose by 15mSv per MRI.

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

Adult women with inoperable cervical cancer

Exclusion criteria

* Inability of the patient to provide informed consent or legally incompetent/incapacitated to do so,
* Pregnancy
* Patients with a hip prosthesis (due to scatter on CBCT and heating in MRI)
* Cardiac arrythmias, pacemaker/ICD, neurostimulator, insuline pump, cochlear implants, glaucoma, myasthenia gravis
* Metal implants in region of interest, metal implants before 1995
* Intracranial clips before 1995
* Occupation as metal worker
* Claustrofobia
* Tricyclic antidepressants

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2014
Enrollment:	33
Type:	Actual

Medical products/devices used

Generic name:	insertion of 3-4 Visicoil(TM) 3 mm fiducial gold-markers in tumour
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-11-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	12-11-2015
Application type:	Amendment
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	NL44492.018.13