Uterine Cervix repeated Magnetic Resonance Imaging for adaptive treatment planning of cervical cancer radiotherapy. A single-center study

Published: 12-11-2015
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To develop an MRI-guided adaptive radiotherapy workflow for patients with locally advanced cervical cancer, aimed at achieving more precise target coverage and better critical organ sparing.

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

Summary

ID

NL-OMON42497

Source
ToetsingOnline

Brief title
CeReMony

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
Cervical cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: adaptive, cervix, MRI, radiotherapy

Outcome measures

Primary outcome

We will develop a new workflow for MRI-guided adaptive radiotherapy, assessing the accuracy of semi-automatic delineation of target volume and critical organs. Treatment remains according to standard clinical practice, but we will (digitally) simulate our new workflow using the acquired MRI scans.

Secondary outcome

NA

Study description

Background summary

Standard therapy for locally advanced cervical cancer (International Federation of Gynecology and Obstetrics (FIGO) stages IB2, IIA2, IIB, IIIA, IIIB, or IVA) [1] is chemoradiotherapy (CRT). Common side effects from this treatment are cystitis, enteritis, proctitis, bone marrow suppression and vaginal stenosis [2-6]. These side effects influence quality of life, and also limit further extension of the radiation fields, and/or the introduction of adjuvant chemotherapy, for high-risk patients.
Adaptive radiotherapy, in which treatment margins are safely reduced using daily imaging, holds great promise for minimization of side effects from radiotherapy. In this study, we want to simulate and develop a new workflow for MRI-guided adaptive radiotherapy. We propose to simulate daily imaging by acquiring three additional MRI scans during regular clinical treatment for locally advanced cervical cancer.

Study objective

To develop an MRI-guided adaptive radiotherapy workflow for patients with locally advanced cervical cancer, aimed at achieving more precise target

coverage and better critical organ sparing.

Study design

Single-center observational study investigating the potential of an MRI-guided adaptive radiotherapy workflow for patients with locally advanced cervical cancer.

Study burden and risks

Three extra MRI scans (without contrast agents) will be acquired taking a total of 80 minutes extra time. This procedure is considered to be free of any risks. No extra hospital visits are required. The treating physician will evaluate the clinical treatment plan using the additional MRI scans during treatment; in some cases this may result in treatment plan adaptation which may lead to patient benefit.

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

* Clinical indication for chemoradiotherapy with curative intent (one of the following):
-FIGO [1] stage IA, IB1 or IIA1 cervical cancer with regional lymph node pathology,
-FIGO stage IA, IB1 or IIA1 cervical cancer with contraindications for surgery
-FIGO stage IB2, IIA2, IIB, IIIA, IIIB, or IVA cervical cancer
* Medical condition that allows chemoradiotherapy with curative intent
* Age * 18 years
* Signed informed consent, obtained before the acquisition of the first additional MRI scan
* Able to comply with the variable bladder filling protocol (drinking and voiding instructions, this protocol is part of standard clinical care)

Exclusion criteria

* Patients who meet exclusion criteria for MRI at 1.5T following the protocol of the department of Radiology of the UMC Utrecht
* Patients who are mentally or otherwise disabled and/or considered legally incapable
* History of previous pelvic radiotherapy
* Pregnant or breast-feeding patients

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):	25-05-2016
Enrollment:	20

Type:	Actual

Ethics review

Approved WMO Date:	12-11-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL54660.041.15

Study results

Results posted: 17-10-2019

First publication
17-10-2019