The MPAC-study: validating craniocaudal tumor extension on MRI with histoPAthology in patients with Cervical cancer

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To validate MRI for assessing craniocaudal tumor extension with histopathology using non-rigid egistration. In addition to 3 Tesla magnetic resonance T2-weighted imaging, diffusion weighted imaging (DWI) and dynamic contrast enhanced (DCE) imaging...

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

Summary

ID

NL-OMON43285

Source
ToetsingOnline

Brief title
De MPAC-study

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
cervical cancer, uterine cervical carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: carcinoma, cervix, extension, MRI

Outcome measures

Primary outcome

Craniocaudal primary tumor extension in direction of the uterine fundus on T2 weighted 3T MRI enforced with DWI/DCE compared to histopathology.

Secondary outcome

To establish the correlation of T2 weighted MRI enforced with DCE and DWI with the microscopic tumor extent in uterine cervical cancer in uterus and parametrium.

Study description

Background summary

Radiotherapy plays an important role in the treatment of loco-regional advanced uterine cervical cancer. Guidelines for radiation prescribe the following radiation targets: The whole uterus including corpus, cervix and parametrium on both sides, and pelvic lymph nodes. Irradiating the whole uterus including a margin for its possible positions in multiple fractions of radiotherapy results in a large treatment field including small bowel and bladder as organs at risk. This in turn results in both short term and long term side effects like radiation enteritis and cystitis, nausea and fibrosis. Reducing the irradiated volume by excluding the fundus of the uterus would decrease the severity and occurrence of the side effects. For this, better pretreatment knowledge on the extent of the primary tumor is needed. The previously conducted feasibility study proved its feasibleness.

Study objective

To validate MRI for assessing craniocaudal tumor extension with histopathology using non-rigid egistration. In addition to 3 Tesla magnetic resonance T2-weighted imaging, diffusion weighted imaging (DWI) and dynamic contrast

enhanced (DCE) imaging will be added with the intention to proceed to a prospective observational study to establish the macroscopic and the appropriate margin to cover for microscopic tumor in uterine cervical cancer on MRI. Furthermore a CT of the resected uterus will be needed to facilitate non-rigid registration.

Study design

A prospective observational study of validation. Patients who participate in this study will undergo a preoperative T2/DWI/DCE MR scan. After the Wertheim-Okabayashi surgical procedure a CT-scan of the uterus will be made. Treatment protocols are based on routine clinical assessment, MRI and histopathology and not altered after the fusion of MRI and histopathology.

Study burden and risks

The burden is minimal; patients participating have to visit the hospital once to undergo the usual T2-weighted MRI added with an extra sequence for DWI and DCE; maximally two weeks preoperatively. The scan will take an additional 20 minutes with the usual 30 minutes. Furthermore gadolinium based contrast will be administered, patient at risk for nephropathy will be excluded. No additional side-effects or risks have been reported on MR imaging, some patients may experience claustrophobia.

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 a carcinoma of the cervix for whom a Wertheim surgical procedure is planned. They must be older than 18 years of age and have a WHO status of 0 or 1.

Exclusion criteria

Exclusioncirteria are MRI related. Patients with claustrophobia, a pacemaker, medicine pump, neurostimulator, cochlear implants, other metal implants in the pelvis wich would disturb the image. In some cases surgical clips in the brain are contra-indicated, this will be evaluated conform standard protocol. Patients with a GFR < 30 ml/min/1,73 m² wil be excluded.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-05-2013
Enrollment:	45

Type:	Actual

Ethics review

Approved WMO Date:	18-04-2017
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	NL59623.018.16

Study results

Date completed:	24-01-2017
Results posted:	29-08-2018
Actual enrolment:	41

First publication
28-08-2018