MPAC-study: A feasibility study of the co-registration of MRI-imaging with PAthological assessment of primary tumor extension in patients with uterine Cervical tumors.

Published: 11-07-2012
Last updated: 26-04-2024

The objective of this study is to investigate the faesibility to fuse images of patholocial anatomy after uterusextirpation according to Wertheim-Okabayashi into tyhe pre-operative T2/DWI/DCE weighted MR images using non-rigid co-registration.

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

Summary

ID

NL-OMON37645

Source
ToetsingOnline

Brief title
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

The feasibility of co-registration of the microscopic images of the surgical

specimen into the T2 MRI images will be evaluated.

Secondary outcome

The secondary endpoint of the study is the correlation of the tumor extend in

uterus and parametria on MRI and microscopic images.

Study description

Background summary

Radiotherapy plays an important role in the treatment of loco-regional cervix 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 side effects like nausea, vomiting and fibrosis. Reducing the irradiated volume by excluding the fundus of the uterus in selected cases would decrease the severity and occurrence of the side effects. For this, better pretreatment knowledge on the extend of the primary tumor is needed. MRI seems a promissing tool for assessing the extend of the primary tumor but has not been validated yet. Furthermore DWI and DCE seems to be useful for this purpose next to the regular T2 weighted images in MRI.

Study objective

The objective of this study is to investigate the faesibility to fuse images of

patholocial anatomy after uterusextirpation according to Wertheim-Okabayashi into tyhe pre-operative T2/DWI/DCE weighted MR images using non-rigid co-registration.

Study design

A prospective observational feasibility study.

Study burden and risks

The burden is minimal; patients participating have to visit the hospital once to undergo the MRI-scan with gadolinium contrast with the usual T2 weighted imaging and de extra added DWI and DCE; maximally two weeks preoperatively. The scan usual scan lasts 15 minutes, the extra imaging takes account for an extra 20 minutes of scanning. Few patients can experience a headache or nausea due to the gadolinium. Some patients with claustrophobia may experience fear.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105 AZ
NL

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:	Recruitment stopped
Start date (anticipated):	17-05-2013
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2012

Application type:	First submission
Review commission:	METC Amsterdam UMC
Not approved Date:	07-03-2014
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	NL39945.018.12

Study results

Date completed:	24-01-2017
Actual enrolment:	15

Summary results
Trial is onging in other countries