Repetitive Functional Imaging in Locally Advanced Cervical Cancer

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Primary: • To evaluate the sensitivity and specificity of DWI-MRI to identify patients who will develop local failure after radio-chemotherapy of cervix cancer.Secondary: • To evaluate the sensitivity and specificity of MRI techniques including (T2-...

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

Summary

ID

NL-OMON40266

Source
ToetsingOnline

Brief title
Functional Imaging in Cervical Cancer

Condition

- Reproductive neoplasms female malignant and unspecified
- Cervix disorders (excl infections and inflammations)

Synonym
Cervix cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: EU Dr Therapat;FP7;projectnr 600852

Intervention

Keyword: cervix cancer, MRI

Outcome measures

Primary outcome

• To evaluate the sensitivity and specificity of DWI-MRI to identify patients who will develop local failure after radio-chemotherapy of cervix cancer

Secondary outcome

• To evaluate the sensitivity and specificity of MRI techniques including (T2-weighted MRI, DCE-MRI) to identify patients who will develop local failure after radio-chemotherapy of cervix cancer

• Determining whether there are differences in bias between centres. The difference in bias will be assessed for the T1 and T2 scans and the Ktrans and ADC maps.

• Comparison of DWI and T2 tumour volume delineation

Study description

Background summary

The Apparent Diffusion Coefficient (ADC) acquired by Diffusion Weighted Imaging (DWI-MR) has been shown to correlate with cellular density. The ADC is indicative of Gross Tumour Volume (GTV), and preliminary data shows that the dynamics of DWI volumes during treatment (shrinkage) as well as dose to DWI volumes has impact on treatment outcome.
Hypoxic tumour cells within the primary tumour have been identified to have prognostic importance for local control Tumour hypoxia is caused by insufficiency of the tumour vasculature leading to both chronic diffusion limited and acute flow limited hypoxia. Radioresistant hypoxic cells diminish the rate of local control, and the hypoxia driven increase in metastatic potential of the tumour and lowers the rate of distant disease control.
Functional imaging has the potential to visualise radioresistant tumour

subvolumes. Dynamic contrast enhanced (DCE) MR imaging has been used to quantify the extent of poor perfusion regions within cervical tumours.

Study objective

Primary:
• To evaluate the sensitivity and specificity of DWI-MRI to identify patients who will develop local failure after radio-chemotherapy of cervix cancer.

Secondary:
• To evaluate the sensitivity and specificity of MRI techniques including (T2-weighted MRI, DCE-MRI) to identify patients who will develop local failure after radio-chemotherapy of cervix cancer
• Determining whether there are differences in bias between centres. The difference in bias will be assessed for the T1 and T2 scans and the Ktrans and ADC maps.
• Comparison of DWI and T2 tumour volume delineation

Study design

observational prospective, non-randomized study

Intervention

The standard MRI scan which will be repeated 3 times extra (before start RT and twice in FU). All other MRIs are part of regular clinical procedures but have as extra the administration of 15 ml contrast

Study burden and risks

Patient will have an extra 3 MRI scans. In all MRI scans (standard as extra) 15 ml of the contast agent Dotarem will be adminstrated. No adverse reaction are known but an allergic reaction can not be ruled out.
The scans will be done during regular hospital visits but extend the visits with 40 minutes

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 locally advanced cervical cancer FIGO stage IB2-IV referred for definitive radio-chemotherapy
• Patients where MR guided brachytherapy is part of standard patient treatment
• Patients without previous record of allergic reaction to infusion of protocol related contrast media (Gadolinium-based for MR-imaging)
• Patients with sufficient kidney function according to local regulations
• Patients of 18 years age and over
• Cancer of the uterine cervix considered suitable for curative treatment
• Positive biopsy showing SQ, AdCA, AdAQ.
• Staging according to FIGO and TNM performed
• MRI pelvis at diagnosis available
• MRI, CT or PET-CT retroperitoneum and abdomen at diagnosis available
• MRI pelvis with applicator at BT will be performed
• Patient informed consent

Exclusion criteria

• Patients receiving neoadjuvant chemotherapy, hyperthermia or other antineoplastic treatments
• Patients with contra indications to MRI

• GFR < 30 ml/min/1.73 m2
• Patients with active infection or severe medical condition
• Patients pregnant, lactating or with childbearing potential without adequate contraception.
• Other primary malignancies
• Metastatic disease beyond paraaortic region (L1-L2)
• Previous pelvic radiotherapy
• Previous total or partial hysterectomy
• Combination of preoperative radiotherapy with surgery
• Patients receiving Brachytherapy (BT) only
• Patients receiving External Beam Radio Therapy only
• Contra indication to BT

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	08-07-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL47482.031.13