Detection of loco-regional invasion of cervical cancer with 7 Tesla MRI

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To develop and in vivo optimize T2w ultra high field (7T) MRI sequences, which use a combination of an endorectal and external coil, to image the (para)cervical area for assessment of the loco-regional tumor status in cervical cancer.

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

Summary

ID

NL-OMON39117

Source
ToetsingOnline

Brief title
DETECT study

Condition

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

Synonym
carcinoma of the cervix uteri, 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: 7T MRI, cervical cancer, loco-regional invasion

Outcome measures

Primary outcome

Optimized T2w ultra high field (7T) MRI sequences of the (para)cervical area

which allow qualitative assessment of the loco-regional invasion of cervical

cancer.

Secondary outcome

Not applicable.

Study description

Background summary

In the Netherlands, the absolute incidence of cervical cancer is approximately 720 patients per year, with an overall mortality of 28.6%. The accurate assessment of local cervical cancer spread (i.e. invasion) is of clinical importance for staging and treatment considerations. For example, if parametrial invasion is absent, radical surgery is the treatment of choice for tumors less than 4cm in diameter. However, if such invasion is present, the patient has become inoperable and (chemo)radiotherapy is warranted. Unfortunately, regular 1.5T MRI as a part of staging work-up has a limited accuracy for detecting loco-regional tumor invasion. Due to relatively frequent false-negative findings a risk of understaging and under-treatment occurs. For such cases adjuvant treatments with (chemo)radiotherapy are indicated after the initial surgery, causing increased morbidity and treatment associated risks. For higher stages, with primary (chemo)radiotherapy, a more reliable MRI based delineation of local tumor spread could enable individualized dose(volume) and field modifications.

Study objective

To develop and in vivo optimize T2w ultra high field (7T) MRI sequences, which use a combination of an endorectal and external coil, to image the (para)cervical area for assessment of the loco-regional tumor status in

cervical cancer.

Study design

The proposed study is an investigator initiated, single center, prospective pilotstudy. The 7T MR Imaging in cervical cancer patients is added to unaltered clinical care. Treatment(choices) is/are not part of the study, the physician will perform standard clinical care.

Study burden and risks

Subjects partaking in this study will not directly benefit from their participation.

Ultimately, in case of a positive study outcome, future patients may benefit from a ultra high field MR Imaging protocol developed by this study. Hence, participation is on an altruistic basis. Standard clinical care is given regarding the staging work up, with the 7T MRI added. The additional risks are considered negligible for the subjects. Standardized UMC Utrecht 7T MRI checklists will be in effect to ensure that no subject with a contra-indication to 7T MRI is scanned. This includes a urine pregnancy test in premenopausal women. This study does not prescribe the use of medication or any MRI contrast agent. The use of an endorectal coil (i.e. antenna) may yield feelings of embarrassment, but is not painful or dangerous. Single use, sterile catheters will cover the antenna during insertion. The study protocol is specifically designed for safe and hygienic use of the coil as well as to maximize the subject*s sense of privacy. The images created by 7T MRI will not be reviewed in a regular clinical fashion, however, incidental findings are reported to the treating physician. The treating physician is unrestricted in his/her treatment possibilities.

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

Histologically proven primary malignancy of the cervix uteri;
FIGO stage IB1, IB2, IIA or IIB;
>=18 years;
Written inform consent provided.

Exclusion criteria

Contra-indications for MRI:
o Any non-removable electronic or ferromagnetic object present in the body;
o Pregnancy;
o Severe claustrophobia;
o Unable to lie still and completely horizontal for minimally 45 minutes;
o Body weight >150kg;
Any type of neo-adjuvant chemo- and/or radiotherapy for cervical cancer;
Uterine prolapse with C >= -6 cm (POP-Q).

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):	31-03-2014
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	endorectal MRI coil
Registration:	No

Ethics review

Approved WMO

Date:	19-02-2014
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	NL41056.041.13