

Accuracy of diffusion weighted MRI in detecting residual tumor in patients conservatively treated for cervical carcinoma.

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To determine the accuracy of MRI with DWI in detecting residual disease in patients with uterine cervical cancer treated with (chemo)radiotherapy. To determine the additional value of using DWI to a standard MRI protocol. To evaluate in the inter-...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cervix disorders (excl infections and inflammations)
Study type	Observational non invasive

Summary

ID

NL-OMON39623

Source

ToetsingOnline

Brief title

MRI-DWI in cervix carcinoma

Condition

- Cervix disorders (excl infections and inflammations)

Synonym

cervical carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Fonds Nuts OHRA

Intervention

Keyword: cervix carcinoma, MRI-DWI

Outcome measures

Primary outcome

To determine the accuracy of MRI with DWI in detecting residual disease in patients with uterine cervical cancer treated with (chemo)radiotherapy.

To determine the additional value of using DWI to a standard MRI protocol.

To evaluate in the inter-reader variability in reading DWI images in the post-treatment setting.

Secondary outcome

na

Study description

Background summary

High stage cancers of the uterine cervix are treated with curative intention, by radiotherapy, in combination with neoadjuvant or concomitant chemotherapy or with hyperthermia [1]. After completion of this treatment, 10 to 20 percent of the patients still have residual tumor in the cervix [2]. Indeed, a recent article from Vincens et al indicated histopathological evidence of residual cervix tumor in no less than 36.5 % of the cases [3].

Early detection of residual tumor will likely enhance patient survival since a salvage hysterectomy can be performed [2]. A retrospective study found that salvage surgery cured 38% of patients with central residual tumor [2], and the authors debated whether more extensive surgery in selected patients might be beneficial and improve this number. Residual tumors detected at a later stage (i.e. when clinically manifest) often need more elaborative therapies with far-going quality of life effects, like a total exenteration (exenteration of bladder, uterus, vagina and rectum). However, these patients are often directed for palliative procedures. Not only patient perspective but also the financial cost are significantly augmented hereby.

It is unclear what procedures are best used to assess tumor status after treatment. Clinical investigation is hampered by the fibrosis resulting from radiation therapy, and biopsy has a high rate of false negatives. In a study by Nijhuis et al, clinical examination with biopsies had a sensitivity of slightly more than 50% [2].

MRI is superior over CT scanning for the evaluation of the cervical region and is now used as a standard technique used for pretreatment evaluation of the cervical region[5]. Very recently guidelines of the European Society of Urogenital Radiology are published that encompass clinical examination and post treatment MR evaluation [6]. MR criteria for a complete response include;

- no lesions seen in the cervix or in the adjacent anatomic areas
- homogeneous hypointense cervical stroma
- Homogeneous and delayed intravenous contrast medium uptake of the cervix after IV injection.

Recently, MRI with diffusion weighted imaging (DWI) was introduced with promising results in detecting tumor in comparison with the standard techniques used in MRI [7-9]. DWI is an imaging sequence that can be used in combination with the standard sequences, and it takes only several minutes additional time. The local tissue diffusion of cervical cancer proved to be significantly different from normal cervical tissue, as shown by McVeigh et al [8]. The most important improvement compared to standard MRI is the better differentiation between tumor and fibrosis and edema, since only the first appears bright on MRI-DWI. It is unlikely that radiation therapy influences the applicability of DWI-MRI. In rectal tumors, this technique is even used during radiation therapy [10]. Indeed, shortly after finishing radiotherapy, edema is present in the tissues, and this improves the discriminating properties of particularly MRI-DWI; in DWI edema is suppressed with better delineation of the high intensity tumor; therefore even small residual tumor areas might be detected. This edema might explain the relatively poor performance of standard MRI in the detection of small tumor residues, as shown by Hatano et al., since both tumor and edema are hyperintense on T2-weighted images [11].

According to the recent guidelines of the European Society of Urogenital Radiology it is recommended to perform a MRI after radiation therapy in order to evaluate tumor response. Response evaluation with MRI is then based on conventional MRI sequences with the use of intravenous contrast. DWI findings will not influence the decisions for further diagnosis and treatment since no validation of this technique has been performed until now. We plan to investigate the additional use of DWI in the detection of residual tumor in patients conservatively treated for cervical cancer, above response evaluation by clinical examination combined with conventional MRI with the use of intravenous contrast.

DWI findings will be analysed a year after treatment and will not influence the decisions for further diagnosis and treatment.

In order to have a sufficiently large patient pool for meaningful analysis, we intend to cooperate with another large tertiary center in Europe, namely University Hospitals of Leuven in Belgium. This hospital offers a large patient

cohort, and also vast experience with diffusion imaging.

In a prospective cohort study, the accuracy of MRI-DWI in detecting residual cervical cancer will be assessed. When MRI- DWI proves accurate in detecting residual disease, MRI- DWI can be used as routine follow-up examination. This will prevent unnecessary treatment delay, and improve the selection of patients with potentially salvageable disease.

Study objective

To determine the accuracy of MRI with DWI in detecting residual disease in patients with uterine cervical cancer treated with (chemo)radiotherapy.

To determine the additional value of using DWI to a standard MRI protocol.

To evaluate in the inter-reader variability in reading DWI images in the post-treatment setting

In the Universital hospitals of Leiden, Amsterdam en Utrecht, the second MRI after radiation therapy will be performed as additional investigation. In this situation, the findings of the DWI sequence will not influence the standard care, whilst important findings during the second MRI may alter treatment. This will be based on the conventional sequences and not the DWI sequence.

In the Universital hospitals of Rotterdam and Utrecht, the second MRI after radiation therapy will be performed as part of the standard care. Also in this situation , the findings of the DWI sequence will not influence the standard care, whilst important findings during the second MRI may alter treatment. This will be based on the conventional sequences and not the DWI sequence..

Study design

Prospective multicenter observational study

Study burden and risks

no burden, no risks, no benefit

Contacts

Public

Erasmus MC, Universitair Medisch Centrum Rotterdam

s-Gravendijkwal 230

Rotterdam 3015CE

NL

Scientific

Erasmus MC, Universitair Medisch Centrum Rotterdam

s-Gravendijkwal 230
Rotterdam 3015CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Recent history of cervical cancer
- Patients treated with radiation therapy with curative intent, with or without concomitant chemotherapy or hyperthermia.
- Age ≥ 18 years
- Informed consent

Exclusion criteria

- Pregnancy
- Contra-indications for general anesthesia
- Contra-indications for MRI (incl. Claustrophobia, metal implants, renal insufficiency, etc.)
- Incapacity of judgement

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-02-2011

Enrollment: 120

Type: Actual

Ethics review

Approved WMO

Date: 24-01-2011

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 01-08-2013

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date: 05-03-2014

Application type: Amendment

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL32659.078.10