# Quantitative MR imaging in locally advanced cervical cancer

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Primary: To evaluate the sensitivity and specificity of dynamic contrast enhanced (DCE-MRI) to identify patients who have increased risk of disease recurrence (local, nodal, systemic) after radio-chemotherapy of cervix cancer.Secondary: To apply…

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Miscellaneous and site unspecified neoplasms benign |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON55543

**Source**
ToetsingOnline

**Brief title**
IQ-EMBRACE

### Condition

- Miscellaneous and site unspecified neoplasms benign
- Cervix disorders (excl infections and inflammations)

**Synonym**
Cervical cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cervical cancer, Funtional MRI

## Outcome measures

### Primary outcome

Kinetic modelling will be applied in DCE-MRI images to assess quantitative kinetic parameters in the gross tumour volume related to blood volume, interstitial volume, flow and permeability. It will be tested whether different thresholds of haemodynamic parameters can predict disease free survival.

### Secondary outcome

We will investigate the use of machine learning techniques such as radiomics and deep learning in computer aided detection (CAD) of the primary lesion. The features used for this task will comprise of the full set and subsets of the functional and textural parameters extracted from DWI, DCE and qT2. The accuracy of the learned algorithm will be evaluated on a separate validation set with expert delineated primary lesion or a leave-one-out-cross validation. Furthermore the DWI and qT2 will be tested whether they may predict disease free survival separately. The combination of all extracted functional (DCE, DWI, qT2) and textural features will be used to train a machine learning algorithm separating the classes: patients with and without disease free survival.

Potential bias between centres will be evaluated for quantitave T2, quantitative DWI and DCE MRI parameters using ANOVA analysis. For DWI: the ADC (median tumour values) will be evaluated for assessment of any center-effect.

# Study description

### Background summary

Hypoxic tumour cells within the primary tumour have shown prognostic importance for local and metastatic disease control in several cancer sites.
Radioresistant hypoxic cells diminish the rate of local control, and the hypoxia driven increase in metastatic potential of the tumour lowers the rate of distant disease control. DCE MRI has been used to quantify the extent of poor perfusion regions within cervical tumours and it has been shown to be a surrogate of hypoxia. Furthermore, a number of studies have demonstrated that DCE MRI is predictive of disease failure in cervix cancer.
The EMBRACE II study will implement an imaging sub-study, which will evaluate the value of quantitative MR imaging to identify patients at increased risk of disease recurrence (local, nodal and systemic).

### Study objective

Primary: To evaluate the sensitivity and specificity of dynamic contrast enhanced (DCE-MRI) to identify patients who have increased risk of disease recurrence (local, nodal, systemic) after radio-chemotherapy of cervix cancer.
Secondary: To apply radiomics for identification of patients who have increased risk of disease recurrence (local, nodal, systemic) after radio-chemotherapy of cervix cancer. Radiomics analysis will include features from DCE-MRI, DWI and quantitative T2 imaging.
Secondary: To correlate MR imaging parameters with biomarkers based on pathology (immunohistochemistry, genomic analysis), in a subgroup of patients
Secondary: To evaluate the implementation of quantitative imaging in a multicentre setting.

### Study design

This is an observational prospective, non-randomized study in which patients with locally advanced cervical cancer included in the EMBRACE II study can enroll. The study will be carried out in 8-15 EMBRACE centres.
MRI will be carried out prior to radiotherapy. The details of the MRI exams will differ from standard clinical practice in the centres, but will be consistent with international guidelines for cervix MRI. The exam will include T1, T2, diffusion, and dynamic contrast-enhanced imaging. At time of brachytherapy, the treatment planning MRI will additionally include DWI and qT2.
Patients will be followed up according to the EMBRACE II follow-up schedule.

### Study burden and risks

For the standard DCE-MRI exam, 0.1mmol/kg of the contrast agent Dotarem

(Gadoteric Acid, concentration 0.5M) is administered intravenously where minor patient discomfort may occur.

## 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 included in the EMBRACE II study (see inclusion criteria in the EMBRACE II protocol)
* Patients without previous record of allergic reaction to infusion of protocol related contrast media (Gadolinium-based)
* Patients with sufficient kidney function according to local regulations

### Exclusion criteria

* According to EMBRACE II protocol
* Patients with active infection or severe medical condition
* GFR < 30 ml/min/1,73 m²

## Study design

### Design

**Study type:** Observational invasive

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 07-12-2018 |
| Enrollment: | 160 |
| Type: | Actual |

## Ethics review

Approved WMO

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|---|---|
| Date: | 14-05-2018 |
| Application type: | First submission |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

Approved WMO

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|---|---|
| Date: | 17-02-2021 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# 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 |
| --- | --- |
| ClinicalTrials.gov | NCT03210428 |
| CCMO | NL62329.058.17 |