

# Investigation of the signature of recurrence and radiation effects after External-Beam Radiotherapy of prostate cancer on multi-parametric MRI

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Primary objective: • Investigate the signature of recurrent prostate cancer and of radiation effects after external-beam radiotherapy on multi-parametric MRI  
Secondary objective: • Identify imaging features that are characteristic of recurrent...

|                              |   |
|------------------------------|---|
| <b>Ethical review</b>        | Approved WMO  |
| <b>Status</b>                | Recruitment stopped                                   |
| <b>Health condition type</b> | Reproductive neoplasms male malignant and unspecified |
| <b>Study type</b>            | Interventional  |

## Summary

### ID

NL-OMON43978

### Source

ToetsingOnline

### Brief title

MRI at +/- recurrent prostate cancer patients after EBRT

### Condition

- Reproductive neoplasms male malignant and unspecified

### Synonym

prostate cancer

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Antoni van Leeuwenhoek Ziekenhuis

**Source(s) of monetary or material Support:** eigen afdeling

## Intervention

**Keyword:** MRI, prostate cancer, radiotherapy

## Outcome measures

### Primary outcome

Investigate the signature of recurrent prostate cancer and of radiation effects after external-beam radiotherapy on multi-parametric MRI

### Secondary outcome

NA

## Study description

### Background summary

External beam radiation therapy (EBRT) is a commonly used treatment modality in localized prostate cancer. However in 27-53% of cases a biochemical relapse occurs and at present these patients are generally managed with palliative treatment options such as androgen deprivation therapy (ADT). In the absence of disseminated disease, focal salvage therapy can be a viable option since it results in decreased toxicity by delivering a localised treatment to the tumour. Hence there is a need for detailed information about tumour location. Multi-parametric MRI (mp-MRI) is already part of the standard screening for primary tumours.

At the time of recurrence the interpretation of images is challenging because prostate tissue is changed by the primary radiotherapy. Fibrosis, inflammation and glandular atrophy are some of the benign confounders present in the irradiated prostate. By using mp-MRI to study patients after radiotherapy both with and without a recurrence we will be able to characterise changes due to irradiation and recurrent disease separately. Biopsies will be used as the gold-standard for local recurrent tumour validation

### Study objective

Primary objective:

- Investigate the signature of recurrent prostate cancer and of radiation effects after external-beam radiotherapy on multi-parametric MRI

Secondary objective:

- Identify imaging features that are characteristic of recurrent prostate cancer
- Identify imaging features that are characteristic of radiation effects after external-beam radiotherapy
- Determine sensitivity and specificity of mp-MRI in detecting recurrent prostate cancer
- Assess the influence of available clinical information on the reading of the images

## **Study design**

Cross-sectional study, with matched cohorts

## **Intervention**

multi-parametric MRI

## **Study burden and risks**

Patients and controls undergo the multi-parametric-MRI examination one time. In the standard exam, 15 ml contrast DOTAREM (Gadoteric acid 0.5m) is administrated i.v.. No side effects are known of this agent. However, an allergic reaction can not be excluded but manageable to treat.

## **Contacts**

### **Public**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

case group:- Biochemical failure, more than 24 months after completion of prior EBRT for treatment of prostate cancer;control group:

- Completion of prior EBRT for treatment of prostate cancer more than 24 months ago without biochemical failure

### Exclusion criteria

- Hormonal treatment in the past year
- Patients who use anticoagulants and can not stop this temporarily for taking biopsies
- Contra-indications for an MRI exam according to the standard protocol for the screening of patients with prostate cancer
- Other treatments for cancer in the pelvis

## Study design

### Design

|                     |                                 |
|---------------------|---------------------------------|
| Study type:         | Interventional                  |
| Intervention model: | Other                           |
| Allocation:         | Non-randomized controlled trial |
| Masking:            | Open (masking not used)         |
| Control:            | Active                          |
| Primary purpose:    | Diagnostic                      |

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 17-12-2015          |
| Enrollment:               | 90                  |
| Type:                     | Actual              |

## Ethics review

|                    |                  |
|--------------------|------------------|
| Approved WMO       |                  |
| Date:              | 16-04-2015       |
| Application type:  | First submission |
| Review commission: | METC NedMec      |
| Approved WMO       |                  |
| Date:              | 15-01-2016       |
| Application type:  | Amendment        |
| Review commission: | METC NedMec      |
| Approved WMO       |                  |
| Date:              | 15-06-2016       |
| Application type:  | Amendment        |
| Review commission: | METC NedMec      |

## 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

CCMO

### ID

NL52307.031.15

## Study results