# Detection of local recurrence with multiparametric MR imaging in prostate cancer patients: a pilot study

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To determine the diagnostic accuracy of multimodality MRI in detecting locally recurrent prostate cancer two years after treatment with external beam radiation therapy.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Prostatic disorders (excl infections and inflammations) |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON32853

**Source**
ToetsingOnline

**Brief title**
Prostate cancer recurrence detection with MR imaging

### Condition

- Prostatic disorders (excl infections and inflammations)

**Synonym**
to find prostate cancer recurrence in the prostate

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** local recurrence, MR imaging, prostate cancer

## Outcome measures

### Primary outcome

To determine the diagnostic accuracy (area under the receiver-operating characteristic curve) of 3 tesla multiparametric MRI in detecting locally recurrent prostate cancer two years after treatment with external beam radiation therapy.

### Secondary outcome

To determine the combination of modalities that will optimize the diagnostic accuracy in the detection of local recurrence.

# Study description

### Background summary

Approximately 30% of patients with newly diagnosed prostate cancer undergo external beam radiation therapy (EBRT) as initial definitive treatment, 50% of which develop biochemical failure (rising prostate specific antigen after nadir) after 5 years, presumably due to disease recurrence. Local recurrence may be amenable to salvage therapy, while systemic recurrence may be an indication for systemic treatment. Local control is usually assessed with transrectal ultrasound (TRUS) guided biopsy, but this is invasive and has limited accuracy after radiation. Ultimately, aggressive assessment of local control 2 years after external beam radiation therapy might allow for earlier salvage therapy and better long-term outcome. The emergence of novel local salvage therapeutic options, such as high intensity focused ultrasound, thermotherapy or cryo-therapy, is an additional factor driving the increased interest in early and more detailed evaluation of local control. Evaluation of local control in the radiated prostate gland by T2-weighted magnetic resonance (MR) imaging is limited by treatment changes, but several reports suggest MR spectroscopic imaging (MRSI), which detects abnormal metabolism rather than abnormal anatomy, is accurate in this setting. It is conceivable that other functional MR imaging techniques, such as diffusion-weighted (DW) MR imaging

(assessing tissue microstructure organization) and dynamic contrast-enhanced MR imaging (assessing microvasculature) will yield similar results. The ability to detect or exclude local recurrence within the prostate by multimodality MR imaging could facilitate salvage local treatment, or potentially facilitate systemic therapy in patients with presumed distant failure based on biochemical failure in the absence of detectable local recurrence, ultimately improving the care and lives of patients with prostate cancer.

### Study objective

To determine the diagnostic accuracy of multimodality MRI in detecting locally recurrent prostate cancer two years after treatment with external beam radiation therapy.

### Study design

Prospective, non-randomized, single centre pilot study. Fifty patients will be included in this pilot study.

### Study burden and risks

MR imaging may cause some discomfort, such as feelings of claustrophobia and discomfort due to loud sounds of the MR instrument during the study. Patients are screened for prior claustrophobic symptoms using the same screening form described above to search for metal device and foreign bodies. Earplugs are provided to all patients in order to minimize the discomfort related to the loud noise.
A topical anesthetic gel will be applied as lubricant at the time of the digital rectal examination.

## 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

- Definite treatment of prostate cancer with EBRT.
- 2 years after radiotherapy treatment

## Exclusion criteria

- Patients unable to undergo MR imaging, including those with contra-indications.
- Contra-indications to MR -guided biopsy.
- Initiation of salvage therapy prior to MR imaging.

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |

| | |
|---|---|
| Start date (anticipated): | 01-03-2009 |
| Enrollment: | 50 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | biopsy needle |
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 26-01-2009 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

## 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 | NL24780.091.08 |