

# Clinical feasibility of a MRI guided robotic system for implantation of position verification markers in the prostate prior to radiotherapy.

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The goal of this project is to investigate the clinical feasibility of the robotic MRI-guided implant system for the implementation of fiducial gold markers for position verification for external beam radiation (or Intensity Modulated Radiotherapy (...)

<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-OMON31479

### Source

ToetsingOnline

### Brief title

Clinical feasibility of a MRI guided robotic implant system.

### Condition

- Reproductive neoplasms male malignant and unspecified

### Synonym

prostate cancer, prostate carcinoma

### 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:** Magnetic Resonance Imaging (MRI), Prostate cancer, Radiotherapy, Robotic implant system

## Outcome measures

### Primary outcome

We consider this intervention feasible if none of the patients suffer from grade 3 toxicity or more as a consequence of the intervention (as defined by the Common Toxicity Criteria Version 3.0 (CTC) for a selection of categories). In addition, a decrease in quality of life (QoL) score (following Rand-36, QLQ-C30 and QLQ-PR25 questionnaires) not more than mean 10 points from baseline for the total group, is considered to be acceptable. Pain will be evaluated using the visual-analogic scale (VAS).

### Secondary outcome

Not applicable.

## Study description

### Background summary

In the process of diagnosis and treatment of patients with prostate cancer, several manual interventions are guided by transrectal ultrasound (TRUS). We have developed a MRI guided single needle robotic implant system to replace this method. This new system offers new and better possibilities in the diagnosis and treatment of prostate cancer. Under MRI guidance, we expect prostate biopsies, placement of position verification markers, external beam radiation and brachytherapy to be performed more accurate and with fewer side effects than formerly. This may result in higher tumour control rates and less toxicity. We begin the clinical introduction of the robotic system with the implantation of position verification markers for external beam radiation, as for this purpose the exact location of the markers is not critical for

treatment outcome.

## **Study objective**

The goal of this project is to investigate the clinical feasibility of the robotic MRI-guided implant system for the implementation of fiducial gold markers for position verification for external beam radiation (or Intensity Modulated Radiotherapy (IMRT)) treatment, in patients with prostate cancer.

## **Study design**

Intervention study.

## **Intervention**

20 patients will receive three gold markers by the robotic MRI-guided implant system.

## **Study burden and risks**

The associated risk includes extra toxicity caused by the robotic system, and a decrease in quality of life during and direct after the intervention. However, based on preliminary results, tapping of the needle by the robotic system is expected to cause less pain and tissue deformation than the conventional manual method.

A benefit associated with participation is a decreases risk of marker implantation outside of the prostate, e.g. through the rectal wall, a complication that is sometimes caused by the conventional method.

## **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

Presence of biopsy proven prostate carcinoma and indication for external beam radiotherapy and therefore gold marker implantation (tumour stadium T1-2N0M0 and no possibilities for brachytherapy or tumour stadium T3N0M0, plus a sufficient physical condition defined as a Karnofsky score >70 percent).

### Exclusion criteria

- Contra-indication for MR imaging (following the UMCU Radiology protocol, see also page 13 of the study protocol)
- Claustrophobia
- Artificial hip replacement
- Contra-indication for gold marker implantation: Use of anti-coagulants which cannot be stopped prior to intervention, prostate intervention in history (transurethral resection of the prostate) or infection, fistula or wounds in the perineal area.

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL  
Recruitment status: Recruitment stopped  
Start date (anticipated): 03-06-2009  
Enrollment: 20  
Type: Actual

## Ethics review

Approved WMO  
Date: 08-07-2008  
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	NL21143.041.08