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 (...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON31479

Source
ToetsingOnline

Brief title
Clnical 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 then 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

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
Nederland

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