DCE MRI in the follow-up of prostate cancer patients after radiotherapy; a matched case control stuy (Pilot)

Published: 17-03-2009
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To measure the differences of DCE MR images between patients with and without local recurrent prostate cancer in the follow up after primary treatment.

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

Summary

ID

NL-OMON33957

Source
ToetsingOnline

Brief title
Matched case control study.

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: Dynamic contrast enhanced (DCE) MRI, Magnetic resonance imaging (MRI), Prostate cancer, Radiotherapy

Outcome measures

Primary outcome

The main endpoint of this study is the difference between patients with and

without local recurrent prostate cancer, in terms of DCE parameters.

Secondary outcome

A secondary objective is to describe differences in DCE MRI parameters at

various time points in the follow-up.

Study description

Background summary

There is a need for new methods for the early detection of recurrent prostate cancer after primary radiotherapy. Results from prostate biopsy are unreliable and prostatectomy is undesirable. Literature concerning the reliability and the interpretation of DCE MRI after radiotherapy is scarce and some significant difficulties exist. As a result, at this moment objective interpretation of the DCE data on itself is not possible.

Study objective

To measure the differences of DCE MR images between patients with and without local recurrent prostate cancer in the follow up after primary treatment.

Study design

Case-control study (observational, pilot).

Study burden and risks

No extra risk is associated with the MRI exam, which is performed in all patients. All patients have to pay one extra visit for the MRI examination.

Patients with biochemical failure will undergo prostate biopsy following the European Association of Urology (EAU) guidelines. The risk of this biopsy is minimal, and mainly includes infection and bleeding. Generally, individual patients will not benefit from the extra MRI 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

- Prostate cancer and therefore treated with external beam radiotherapy or I-125 implantation in the last 10 years, with a minimum follow-up of 2 years.
- Written informed consent.
Specific inclusion criteria for the case group:
- Biochemical failure as defined by the Phoenix criteria (nadir PSA level + 2 ng/mL)

- Positive prostate biopsy results

Exclusion criteria

Contra-indications for 3T MR imaging following the protocol of the department of Radiology UMCU.
Hormonal treatment < 1 year before inclusion in this study.
Advanced kidney disease.;Specific exclusion for the case group:
Contra-indication for prostate biopsy (for example oral anticoagulants use).

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2009
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	17-03-2009
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	NL25435.041.08