Pilotstudy to characterise prostate tissue using dynamic contrast enhanced (DCE-) MRI in patients with localised prostate cancer.

Published: 10-01-2008
Last updated: 08-05-2024

This is a pilotstudy after characterising prostate tissue by using DCE-MRI in patients with a localised prostate cancer.The relation between DCE-MRI and vasculature and oxygenation will be investigated as a preparation for further studies.

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

Summary

ID

NL-OMON31676

Source
ToetsingOnline

Brief title
The relation between DCE-MRI and prostatectomy specimen

Condition

- Reproductive neoplasms male malignant and unspecified
- Genitourinary tract disorders NEC

Synonym
blood perfusion, prostate cancer

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: cancer, DCE, MRI, prostate

Outcome measures

Primary outcome

The interpretation of the DCE-MRI will be in terms of vasculature, microvessel

density and the amount of vessel leakage.

The first question is whether this interpretation has it's basis in histology.

Secondary outcome

The second question is whtether these histologic characterisations can be

correlated with the presence of tumour and it's oxygenation.

Study description

Background summary

Dynamic contrast enhanced (DCE-) MRI improves the sensitivity ans specificity of the detection of prostate cancer.
Next to the detection of tumour DCE-MRI also is able to produce parameters which can describe vasculature, leakage and micro-vessel density.
Therefore DCE-MRI probably has a major role in characterising tissue.
Cell-differentiation (gleason-score), hypoxia and cell density are prognostically relevant because they might help to differentiate in therapy, like optimising the dose distribution in radiotherapy.
Up to now no studies have been described in characterising prostate tisse by DCE-MRI.

Study objective

This is a pilotstudy after characterising prostate tissue by using DCE-MRI in patients with a localised prostate cancer.

The relation between DCE-MRI and vasculature and oxygenation will be investigated as a preparation for further studies.

Study design

Patients who will receive a prostatectomy will receive one 3.0 T MRI (including a DCE measurement).

Next, histology will be evaluated by the pathologist and results will be quantified.

Study burden and risks

Prior to the prostatectomy an MRI will be made, combined with a bladder catheter and gadolineum contrast intraveniously injected. This is expected to take 45 minutes.

At least two hours before surgery pimonidazole will be administered,

Risks:
§ Gadolineum: this has no known complications.
§ Bladder catheter: infectious cystitus, urethra trauma.

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

Patients who will receive a prostatectomy as treatment for a locallised prostate cancer

Exclusion criteria

No contraindications for a 3.0 T MRI

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	10-01-2008
Application type:	First submission
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	ID
CCMO	NL16190.041.07