Influence of injection time in DCE-MRI in patients with prostate cancer

Published: 23-08-2012
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Influence of Injection time of DCE-MRI for prostate cancer patients with consistent kinetic parameters.

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

Summary

ID

NL-OMON37313

Source
ToetsingOnline

Brief title
influence of injection time

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: afdeling radiotherapie

Intervention

Keyword: DCE-MRI, prostate cancer

Outcome measures

Primary outcome

Establish the influence of injection time of kinetic tracer parameters,

determined with Dynamic Constrast-Enhanced MRI of the prostate.

Secondary outcome

none

Study description

Background summary

DCE-MRI technique can be used to characterize the perfusion of microvascularisature in tissue. Because tumor growth is associated with neovascularization, this technique is valuable for the detection of tumors. To provide accurate detection of small tumors and a precise delineation of a tumor volume. Therefore it is important to determine the influence of injection time with the use of consistent TKA parameters.

Study objective

Influence of Injection time of DCE-MRI for prostate cancer patients with consistent kinetic parameters.

Study design

Patient wil uindergo the standard MRI exam a second time before treatment of prostate cancer

Study burden and risks

Patients will undergo the standard MRI exam a second time. In the standard exam 15 ml of the contrast agent Dotarem (Gadoteric acid , concentration 0.5M) is administrated intravenenously. No adverse effects are known of the administration of a second dose the next week after the regular exam. The

repeat of the MRI exam causes a negligible risk for the patient.

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

biopsy proven prostate cancer
able to undergo MRI

Exclusion criteria

• • Contra-indications for a MRI exam according to the standard protocol for the screening of patients with prostate cancer.

• GFR < 30 ml/min/1.73 m²
• Treatment of prostate cancer prior to the MRI exams.
• Prior hormonal therapy
• Prior trans-urethral resection (TURP)

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):	20-03-2013
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO Date:	23-08-2012
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	05-12-2012
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL40706.031.12