De toegevoegde waarde van magnetic resonance imaging in detectie van prostaatkanker.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21521

Source
Nationaal Trial Register

Brief title
MRI in detectie van prostaatkanker

Health condition

prostate cancer detection, diagnose prostaatkanker

Sponsors and support

Primary sponsor: Radboud University Medical Centre
Department of Radiology
Source(s) of monetary or material Support: Dutch Cancer Society Grant

Intervention

Outcome measures

Primary outcome

Detection rates of MRGB compared to a second or later TRUSGB examination. Timepoint:8 weeks.

Secondary outcome

1. Detection rate of MRUSFGB. Timepoint: 8 weeks;

2. Percentage of patients upgraded(with an increase of one point in Gleason score on MRGB and MRUSFGB compared tot TRUSGB) by MRGB and MRUSFGB Gleason score respectively compared to TRUSGB Gleason score. Timepoint: 8 weeks.

Study description

Background summary

Objective:
To determine detection rates of MRGB comparing to TRUSGB and MRUSFGB within patients who are at risk for prostate cancer but have no histological prove of prostate cancer, and who underwent at least one negative TRUSGB.

Secondary Objectives:
To determine the percentage of patients upgraded for MRGB compared to TRUSGB.
To determine detection rates of MRUSFGB.

Study design: A prospective cohort study.

Study population:
Patients who underwent at least one negative TRUSGB with a PSA¡Ý4 and who are suspected of having prostate cancer without having histological proof of prostate cancer.

Intervention:
Patients will undergo a multimodality MRI consisting of anatomic T2 weighted MRI (T2W), Dynamic Contrast enhanced MRI (DCE) and Diffusion weighted (DWI) MRI. During a second visit a 10 core standard TRUSGB will be taken. Ultrasound images will be fused with processed MR images. After TRUSGB, the examiner will switch to the Fusion mode within the same examination and 2 cores at MRUSFGB of each tumor suspected region (TSR) will be taken up to a maximum of 4 cores (maximum of 2 TSR¡¯s). Deze eerste sessie is dus puur wetenschap, c.q. voor de patienten die specifiek voor MRI biopten komen ¡°voor niets¡±After 4 weeks the patient will undergo MRGB (maximum of 2 cores of each TSR up to a maximum of 4 cores). All specimens will be examined by one specialised pathologist. In each patient one TRUSGB, one MRUSFGB and one MRGB procedure will be performed.

Study objective

MRI leads to higher prostate cancer detection: MR guided prostate biopsy and MR-ULtrasound Fusion Guided prostate biopsy will yield higher detection rates in comparison to Transrectal Ultrasound guided prostate biopsy.

Study design

8 weeks after inclusion. After inclusion of all patients necessary.

Intervention

1. MRI examination of the prostate;

2. MR guided prostate biopsy;

3. MR ultrasound Fusion guided prostate biopsy;

4. Transrectal Ultrasound guided prostate biopsy.

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Eligibility criteria

Inclusion criteria

1. PSA¡Ý4.0 ng/ml;

2. One or more previous negative TRUS guided prostate biopsies;

3. Last TRUS guided biopsy should be within one year ago.

Exclusion criteria

1. Patients with known contradictions to MRI;

2. Patients with known contra-indications to Gadolinium based contrast agents;

3. Patients with previous radiotherapy, hormonal therapy or local treatment of the prostate;

4. Patients with histological prove of prostate cancer;

5. Patients with a known restricted renal function (MDRD-GFR value < 30 ml/min/1.73m2) as contraindication for use of intravenous Gadolinium contrast.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Non controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	10-01-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-09-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 32545
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1894
NTR-old	NTR2008
CCMO	NL26080.091.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON32545

Study results

Summary results
N/A