The value of MRI in active surveillance of prostate cancer.

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Incorporation of multimodality MRI will improve patient selection and will lead to earlier detection of patients with progressive disease in active surveillance within the PRIAS study, thus increasing patient safety. In this way, active surveillance...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23734

Bron
Nationaal Trial Register

Verkorte titel
MRI in PRIAS

Aandoening

prostate cancer, prostaatkanker

Ondersteuning

Primaire sponsor: C.M.A. Hoeks, MD
Department of Radiology Radboud University Nijmegen Medical Centre
Overige ondersteuning: Dutch Cancer Society Grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Number of patients that are upgraded on basis of histology specimen Gleason score of initial

and follow-up MRGB (at 2 months, 1 year and 4 years of follow-up) versus histology specimen Gleason score of initial and follow-up TRUSGB (at 1 and 4 years of follow-up). Timepoints 2 months, 1 year and 4 years.

Toelichting onderzoek

Achtergrond van het onderzoek

Objective: to determine if the incorporation of Multimodality MRI including MRGB within the PRIAS study for low-risk low volume prostate cancer leads to a higher number of cancers that is upgraded by follow-up MRGB versus initial TRUSGB (at 2 months, one year and four years of follow-up) in comparison to upgrading of cancers by follow-up TRUSGB versus initial TRUSGB (at one and four years of follow-up).

Study population: Patients included in the PRIAS study
Intervention All the patients will undergo active surveillance with TRUSGB, MRI and MRGB at 2 months (not for TRUSGB), one year and four years of follow-up with further MRI diagnostics in between if necessary.
A minimum of 19 visits, depending on the follow-up time, to the Radboud University Nijmegen medical centre, where TRUSGB, MRI and MRGB will be performed (6), and to the primary health care centre where the patients own urologist is based, to take venapunctions, digital rectal examinations and evaluations (13).

Doel van het onderzoek

Incorporation of multimodality MRI will improve patient selection and will lead to earlier detection of patients with progressive disease in active surveillance within the PRIAS study, thus increasing patient safety. In this way, active surveillance will be reliable in preventing overtreatment (incontinence, impotence).

Onderzoeksopzet

Mainly after 2 months, one year and four years(=total follow-up) of folluw-up.

Onderzoeksproduct en/of interventie

1. PCA3 testing;

2. Magnetic resonance imaging of the prostate;

3. Magnetic resonance imaging guided prostate;

4. Biopsy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Histologically proven adenocarcinoma of the prostate;

2. PSA ¡Ü 10 ng/ml and PSA density <0.2 ng/ml/ml;

3. TRUS-biopsy Gleason Score ¡Ü 6 (no 4 or 5 pattern);

4. TRUS-biopsy characteristics: < 2 cores involved;

5. Clinical stage T1C or T2;

6. Appropriate biopsy sampling (conform PRIAS protocol).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with known contradictions to MRI;

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

3. Patients with previous therapy for prostate cancer;

4. Patients who can not or do not want to receive radiotherapy or radical prostatectomy;

5. Patient request for definitive curative intervention.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	14-09-2009
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-09-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33150
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1893
NTR-old	NTR2006
CCMO	NL27911.091.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33150

Resultaten

Samenvatting resultaten
N/A