Met prostaat MRI Meer Mans

No registrations found.

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

Summary

ID

NL-OMON22730

Source
NTR

Brief title
4M

Health condition

Prostate cancer, molecular urine test, mri prostate, mri guided biopsy, prostate risc calculator, PSA, TRUS biopsy

Dutch: Prostaatkanker, moleculaire biomarker, prostaat risico calculator, MRI, MRI geleide biopsie, echo gelede transrectale biopsie, PSA

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: KWF

Intervention

Outcome measures

Primary outcome

To investigate the additional value of mp-MRI and MRI-guided biopsy in men with an elevated PSA regarding the detection of both insignificant and significant cancer, and reducing biopsies.

Secondary outcome

To determine the cost-effectiveness of such an additional mp-MRI-procedure compared to random TRUS-guided biopsy, which is “standard of care”.

To determine the influence of both procedures on quality of life.

To determine the added value of the prostate risk calculator, Quattro urine test and mp-MRI.

To define the optimal PSA threshold as from 3 ng/ml for proceeding to performing prostate biopsies

To investigate the accuracy of the Gleason scores of positive biopsies in predicting the definite Gleason score of available radical prostatectomy specimens

Study description

Background summary

Rationale: Prostate cancer is the most common malignancy in men in the Netherlands. In 2009, 10,166 new cases were seen with a mortality of 2,492. With an increasing incidence, a growing economic burden presses the community. Furthermore, PSA testing is not specific and subsequent transrectal ultrasound (TRUS) biopsy result in over-diagnosis, and subsequent overtreatment. The disadvantages of PSA have led to the development of multivariate risk prediction tools, for example the Prostate Cancer Risk Calculator based on ERSPC data and the discovery of PCa-specific biomarkers that have a higher specificity for detecting significant prostate cancer and can preferably be obtained through non-invasive methods, for example Quattro urine test,[referentie] It has been shown that MRI and MRI-guided biopsy are accurate in localizing aggressive cancer in selected patient populations. We expect that MRI may also be of additional value in the population of men with an elevated PSA in selectively detecting significant cancers. If so, it will result in a more accurate therapy choice –specifically reduction of overdiagnosis and thus overtreatment– and reduced number of biopsies, with subsequent lower morbidity and lower costs. However, empirical evidence in this population is lacking.
Objective: To investigate the additional value of MRI and MRI-guided biopsy in men with an elevated PSA upon first visit to the urologist regarding the detection of both insignificant and

significant cancer, and the reduction of biopsy numbers. Combined with evaluation of the added value of the prostate risk calculator and Quattro urine test in predicting significant PCa.

Study design: Clinical trial with a follow-up of 24 months.
Study population: Men aged 50-75 years who visit the urologist after PSA screening and have a subsequent PSA ≥ 3 ng/ml.

Intervention (if applicable): Men with an elevated PSA will undergo standard DRE and donate urine for Quattro biomarker analysis, subsequently an MRI and MRI-guided biopsies of MR-suspicious lesions are performed followed by the usually performed random TRUS-guided biopsies.
Main study parameters/endpoints: Primary endpoint: clinical insignificant versus significant cancers detected. Secondary endpoints: health-related quality of life, accuracy of MR-guided biopsies, cost-effectiveness, number of biopsies taken per patient, the added value of the prostate risk calculator and Quattro urine test, defining a cut-off point to undergo prostate biopsies for PSA values above 3 ng/ml.
To study the primary endpoint, the following analyses will be performed: comparison of the pathology outcomes of TRUS- and MR-guided biopsies within the patient group who underwent both biopsies, and comparison of the pathology outcomes of all performed TRUS-guided biopsies and MR-guided biopsies.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: MR imaging may cause some discomfort, such as feelings of claustrophobia and discomfort due to loud sounds of the MR instrument during the study. Patients are screened for prior claustrophobic symptoms using a screening form, which is also used to search for metal device and foreign bodies. Around 330 patients also undergo MR-biopsies (2 to 3 needles), which causes inconvenience and takes more time. The donation of urine for the Quattro urine test does not cause any additional risk and the burden of providing a urine sample is considered to be minimal.

Study objective

We expect that mp-MRI, molecular urine test and Prostate Cancer Risk Calculator may be of additional value in differentiating between significant and insignificant cancers in men with an elevated PSA in the primairy diagnosis. If so, it will result in a better and more accurate diagnosis while needing less biopsy cores, resulting in a more accurate therapy choice with subsequent lower morbidity, an increased quality of life and at lower costs. However, empirical evidence in men with increased PSA is lacking.

Study design

T1: Inventation to participate in trial, Questionnaire set, urine test, prostate risc calculator

T2: MRI scan performed, Questionnaire set, MRI guided biopsy if suspicious lesion is detected.

T3: TRUS guided biopsy, Questionnaire set

T4: Questionnaire set

T5: Questionnaire set

T6: Questionnaire set

Intervention

Men with an elevated PSA will undergo standard DRE and donate urine for urine biomarker analysis, subsequently an MRI and MRI-guided biopsies of MR-suspicious lesions are performed followed by the usually performed random TRUS-guided biopsies.

Contacts

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Eligibility criteria

Inclusion criteria

• Men aged 50-75 years

• PSA ≥ 3.0 ng/ml

• Subject must be able to comprehend and sign an informed consent by patient

• Subject must be able to comprehend and sign an MRI screening form (to search for metal device/foreign bodies/claustrophobia)

• No contraindications for and are eligible to have a MR scan of their prostate utilizing a surface coil

Exclusion criteria

• Impossibility to obtain a valid informed consent

• History of previous prostate biopsy

• Already proven prostate cancer or history of PCa. Patients unable to undergo MR imaging, including those with contra-indications

• Allergic reaction to gadolinium in the past or eGFR <60 ml/min/1.73m2

• Metallic hip implant or any other metallic implant or device that distorts local magnetic field and compromises the quality of MR imaging

• Use of finasteride (PROSCAR®, Propecia®), dutasteride (AVODART®), leuprolide acetate (Lupron Depot®), or other medications or hormones (within the past 3 months) that are known to affect serum PSA levels.

• Symptoms of urinary tract infection (including prostatitis) at the time of enrolment.

• History of invasive treatments for BPH or lower urinary tract symptoms (LUTS), e.g. transurethral resection of the prostate (TURP), heat, laser, or ultrasound treatments in the last 6 months.

• History of illness that the investigator/physician considers to interfere with or affect the conduct, results, and/or completion of the study.

• Participation in a pharmaceutical or treatment-related clinical study or receipt of treatment for a prostate-related condition within the last six months of enrolment.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-02-2015
Enrollment:	660
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-10-2015
Application type:	First submission

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
NTR-new	NL5273
NTR-old	NTR5555

Register ID

Other KUN 2014-6707 (KWF) : Registratie nr 2013-148 Nr. 39544.091.13

Study results

Summary results

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