The added value of MRI for detection of prostate cancer: validation with MR guided biopsies, fusion of MRI and transrectal ultrasound guided biopsies and TRUS guided biopsies.

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To determine detection rates of MRGB comparing to TRUSGB and MR-US-Fusion-GB within patients who are at risk for prostate cancer but have no histological prove of prostate cancer, and who underwent at least one negative TRUSGBTo determine the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive neoplasms female malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON32545

Source
ToetsingOnline

Brief title
Detection of prostate cancer: MRGB, TRUSGB and MRUSFGB

Condition

- Reproductive neoplasms female malignant and unspecified

Synonym
prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: KWF KWO

Intervention

Keyword: biopsy, detection, MRI, prostate

Outcome measures

Primary outcome

Detection rates of MRGB (expected to be over 27%) compared to a second or later

TRUSGB (expected to be 17% or less). Detection rate of MRUSFGB.

Secondary outcome

Percentage of patients upgraded by MRGB and MRUSFGB respectively compared to

TRUSGB.

The mean increase of Gleason score for MRGB and MRUSFGB respectively compared

to TRUSGB.

Predicitive accuracy for MRGB, MRUSFGB and TRUSGB Gleason score for true

prostatectomy specimen Gleason score in case of prostatectomy.

The increase of detection of clinical significant prostate cancers by MRGB and

MRUSFGB in comparison to TRUSGB.

Study description

Background summary

Outcomes of Gleason scores on histopathology of transrectal ultrasound guided prostate biopsy (TRUSGB) remain the basis for urological decisions in treatment of prostate cancer.
Urologists experience great difficulty in making treatment decisions when PSA levels rise in spite of inexistence of cancer in TRUS guided biopsies. This

phenomenon is frequently caused by false positive results of TRUSGB. Moreover also a undersampling exists in TRUSGB to great extent. Because of this cancers that were initially of lower grade are upstaged on repeat biopsies.
Undergrading in TRUS guided biopsies unmistakenly leads to incorrect risk stratification of patients and therefore to incorrect treatment decisions.
MRI has established itself as an accurate technique for localisation and detection of prostate cancer.
Instead of taking random biopsies as in TRUSGB, MRGB and MRUSFUSIONGB can take lesion targeted biopsies. Preliminary results have shown a significant decrease in undersampling of MRGB.
The above leads to the hypothesis that MRGB has a higher detection rate (at least 10% increase) comparing to TRUSGB.

Study objective

To determine detection rates of MRGB comparing to TRUSGB and MR-US-Fusion-GB 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

To determine the percentage of patients upgraded for MRGB compared to TRUSGB.
To determine the mean increase in Gleason score for MRGB compared to TRUSGB.
To determine the predicitive accuracy for true prostatectomy Gleason score for MRGB. MRUSFUSIONGB and TRUSGB for patients that underwent prostatectomy.
To determine detection rates of MRUSFUSIONGB.
To determine correlation of MRUSFUSIONGB and MRGB.

Study design

A prospective cohort study.

Intervention

Patients will undergo a multimodality MRI consisting of T2W, DCEMRI, MRSI and DWI.
During a second visit 12 standard TRUSGB will be taken. Ultrasound images will be fused with processed MR images by another examiner than the examiner taking TRUSGB. After TRUSGB, the examiner will switch to the Fusion mode within the same examination and 3 MRUSFUSIONGB of each TSR will be taken. After 4 weeks the patient will undergo MRGB (3 samples of each TSR).
All specimens will be examined by one specialised pathologist. In case of prostatectomy, prostatectomy specimens GS will en compared to MRGB, TRUSGB and MRUSFUSIONGB GS.

Study burden and risks

For study purposes burden exists of time investment of 3 visits to the

hospital. The burden (heating and noise) of MRI examination. The burden of 6 to 12 extra biopsies (depending on one or two tumor suspected regions: 3 biopsies per region). And the burden of MR guided biopsy: long examination in uncomfortable prone position. Patients benefits allow for this study. Potential patient risks in this study as mentioned complications of biopsy or of magnetic resonance imaging or serious unexpected events and patient burden in form of time investment and possible discomfort of MR examinations and biopsies are outweighed by potential benefits for patients.
Patients will possibly benefit from an earlier detection of prostate cancer, a more accurate biopsy through MR guidance and consequently their individual risk stratification and selection for appropriate curative treatment will be optimalize

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
6525 GA Nijmegen
Nederland
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
6525 GA Nijmegen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• PSA>=4.0 ng/ml
• One or more previous negative TRUS guided prostate biopsies

Exclusion criteria

• Patients with known contradictions to MRI
• Patients with known contra-indications to Gadolinium based contrast agents.
• Patients with previous radiotherapy, hormonal therapy or local treatment of the prostate.
• Patients with histological prove of prostate cancer

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-10-2009
Enrollment:	60
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	19-06-2009

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21521
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL26080.091.08
OMON	NL-OMON21521