

Value of multiparametric MR and MRI-guided biopsies of the prostate in men with an elevated PSA

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To investigate the additional value of MRI and MRI-guided biopsy in men with an elevated PSA in the general practitioners* (GP) practice regarding the detection of both insignificant and significant cancer, and reduced biopsies.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON39439

Source

ToetsingOnline

Brief title

Value of MRI in diagnosing prostate cancer

Condition

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

Synonym

prostate cancer, prostatic carcinoma

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud

Source(s) of monetary or material Support: KWF Kankerfonds (aanvraag ingediend)

Intervention

Keyword: Magnetic resonance imaging, Prostate cancer, Prostate specific antigen

Outcome measures

Primary outcome

Primary endpoint: clinical insignificant versus significant cancers detected.

Secondary outcome

Secondary endpoints: health-related quality of life, accuracy of MR-guided biopsies, cost effectiveness

Study description

Background summary

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 over-treatment. 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 detecting significant cancers in men with an elevated PSA. If so, it will result in a more accurate therapy choice (reduction of over-treatment) with subsequent lower morbidity and lower costs. However, empirical evidence is lacking.

Study objective

To investigate the additional value of MRI and MRI-guided biopsy in men with an elevated PSA in the general practitioners* (GP) practice regarding the detection of both insignificant and significant cancer, and reduced biopsies.

Study design

Clinical trial with a follow-up of 12 months.

Intervention

All men will undergo an MRI-scan. If suspicious lesions are present, also MRI-guided biopsies will be taken. If no abnormalities are seen, no MR-guided biopsies will be performed. Afterwards, all men will undergo regular TRUS-guided biopsies.

Study burden and risks

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. Some patients will undergo biopsies both with MRI and TRUS, which causes inconvenience and takes more time.

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

Men, 50-75 years, PSA > 3 ng/ml

Exclusion criteria

Use of 5-alfareductase inhibitors
Proven prostate cancer

Study design

Design

Study phase:	3
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	13-01-2015
Enrollment:	620
Type:	Actual

Medical products/devices used

Generic name:	MR-guided biopsy
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	17-09-2013

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-09-2014
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-11-2014
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
CCMO	NL39544.091.13