

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

Published: 17-09-2013

Last updated: 25-04-2024

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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Endocrine neoplasms malignant and unspecified
<b>Study type</b>	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**

### **Public**

Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-Zuid 10  
Nijmegen 6525 GA  
NL

### **Scientific**

Universitair Medisch Centrum Sint Radboud

Geert Grooteplein-Zuid 10  
Nijmegen 6525 GA  
NL

## **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