The value of additional MR-Ultrasound fusion guided biopsies to standard Navigo*-based biopsies in the diagnosis of prostate cancer

Published: 11-11-2015
Last updated: 15-05-2024

Primary objectiveTo determine whether adding the MRI/US fusion technique using mpMRI images for directed biopsy of a ROI leads to a higher detection rate of PCa per patient compared to a systematic 12-core biopsy protocol including directed biopsy…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON43620

Source
ToetsingOnline

Brief title
The value of additional MR-Ultrasound fusion guided biopsies

Condition

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

Synonym
prostate cancer prostate malignancy

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: ziekenhuis en maatschap

Intervention

Keyword: MR-Ultrasound fusion, Navigo, prostate biopsies, prostate cancer

Outcome measures

Primary outcome

The number of patients with histological proven prostate cancer;

Secondary outcome

The number of patients with a different Gleason score after adding

MRI-utrasound fusion-guided biopsies.

Study description

Background summary

In spite of the fact that we normally take 12 biopsies in patients in whom we suspect prostate cancer, very often no tumor can be found since the majority of the tumors cannot be visualized in grey-scale ultrasound. On MRI tumors are more often visible and we hope to increase the number of tumors found when we add to the standard biopsy session 1 or 2 extra biopsy in regions of interest assigned by the radiologist. With help of image fusion we can navigate the ultrasound guided biopsies to the ROI found on MRI. This may lead to better and quicker diagnosis of prostate cancer, leading to reduced number of biopsy sessions and number of biopsies per session. Furthermore there will be less delay in definitive treatment of people who are diagnosed with prostate cancer earlier. Possibly a more accurate Gleason grading can be obtained resulting in more accurate work-up and leading to a more tailored treatment advise.

Study objective

Primary objective
To determine whether adding the MRI/US fusion technique using mpMRI images for directed biopsy of a ROI leads to a higher detection rate of PCa per patient compared to a systematic 12-core biopsy protocol including directed biopsy of

ROI on grey scale TRUS images, using the 3D Navigo* system.
Secondary objective
To determine in how many patients adding the MRI/US fusion technique using mpMRI images for directed biopsy of a ROI leads to a different Gleason score compared to a systematic 12-core biopsy protocol including directed biopsy of ROI on grey scale TRUS images, using the 3D Navigo* system.

Study design

Prospective in-patient blinded controlled study

Intervention

There will be no intervention group, it will be an in-patient control study.

Study burden and risks

Patients will have to undergo an MRI before the biopsies. Normally, patients do not have an MRI before biopsies, but many have one after the diagnosis prostate cancer is made. In those cases it is only the timing that is different.
The number of biopsies in participating patients will be 13 or 14 instead of 12. We do not expect the addition of 1 or 2 biopsies to give significant extra morbidity. On the other hand we expect that in a number of patients the tumor will be discovered with the extra biopsy only, thus preventing a second series of biopsies at a later stage. Overall the total number of biopsies in the whole group could be even less than without the protocol.
Since it is an in-patient control study there*s no group bondage.

Contacts

Public
Jeroen Bosch Ziekenhuis

Deuterseweg 1
's-Hertogenbosch 5223GZ
NL
Scientific
Jeroen Bosch Ziekenhuis

Deuterseweg 1
's-Hertogenbosch 5223GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Men aged 50-65 years: PSA * 4 ng/ml - 30 ng/ml
- Men aged 65-75 years: PSA * 10 ng/ml- 30 ng/ml

Exclusion criteria

all contra indications for MRI
all contra indications for prostate biopsies
protocol page 9

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped

Start date (anticipated):	12-01-2016
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2015
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	26-05-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	20-12-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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: 27074
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL51982.028.15
OMON	NL-OMON27074