Navigo™ MR-ultrasound fusion guided biopsies

No registrations found.

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

Summary

ID

NL-OMON27074

Source
Nationaal Trial Register

Health condition

prostate cancer

Sponsors and support

Primary sponsor: Department of Urology
Jeroen Bosch Hospital
's-Hertogenbosch
Source(s) of monetary or material Support: Astellas Research Grant

Intervention

Outcome measures

Primary outcome

Cancer detection rates

Secondary outcome

Gleason score

Study description

Background summary

Despite limitations considering the presence, staging and aggressiveness of prostate cancer, ultrasonography (US)-guided systematic biopsies (SB) are still the 'golden standard' for the diagnosis of prostate cancer. Recently, promising results have been published for targeted prostate biopsies (TB) using magnetic resonance imaging (MRI) and ultrasonography (MRI/US)-fusion platforms. With help of image fusion we are able to navigate the ultrasound guided biopsies to the region of interest (ROI) found on MRI. This may lead to better and quicker diagnosis of prostate cancer. 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

We hypothesize that MRI guided targeted prostate biopsies are equal in finding prostate cancer as systematic biopsies, and even better at finding clinical relevant prostate cancer (>Gleason 6).

Study design

Both interventions will take place on the same day, in the same biopsy session.

Intervention

In-patient control study.

Patients receive both interventions:

- conventional Navigo™-based systematic biopsies (12 cores)

- in case of region of interest on mpMRI: MR-US fusion targeted biopsies (max 4 cores)

Contacts

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Eligibility criteria

Inclusion criteria

Men with clinical suspicion for prostate cancer due to PSA >4 ug/L

Age 50-70 years

Biopsy naive

Exclusion criteria

PSA >30 ug/L

Contra indications for MR

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-01-2016
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-02-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43620
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5014
NTR-old	NTR5787
CCMO	NL51982.028.15
OMON	NL-OMON43620

Study results