Computer-aided ultrasonography (HistoScanning) in men with untreated localised prostate cancer on active surveillance.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON33297

Source
ToetsingOnline

Brief title
PCa HistoScanning and Active Surveillance

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- Prostatic disorders (excl infections and inflammations)

Synonym
Prostate cancer, prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Active Surveillance, HistoScanning, Prostate cancer

Outcome measures

Primary outcome

The main study endpoint is the area under curve for HistoScanning predicting adverse repeat biopsy findings.

Secondary outcome

Time to deferred active treatment, number of positive biopsy cores (systematic and HistoScanning guided), percentage of corresponding quadrants defined by HistoScanning and biopsy, percentage of corresponding quadrants defined by HistoScanning and radical prostatectomy, Kappa coefficient, percentage of corresponding quadrants defined by various HistoScanning procedures, qualitative description of physician questionnaire, number of successful HistoScannings.

Baseline values are age, initial PSA level, clinical tumour stage, free PSA to total PSA ratio, PSA velocity, Gleason score, prostate volume, PSA density and PSA doubling time.

Study description

Background summary

Markers that predict the behaviour of localized prostate cancer are needed to identify patients who require treatment. We hypothesise that, within the group of low-risk disease (as identified by the PRIAS protocol), the initial tumour volume and tumour growth assessed with HistoScanning would be a marker of disease progression.

Study objective

The primary objective is to compare the sensitivity and specificity of tumour size and growth assessed with HistoScanningTM with the PRIAS parameters (PSA changes). The sensitivity and specificity of both methods will be measured with adverse biopsy findings as golden standard.
Secondary objectives are to assess the correlation of HistoScanning results and time to deferred treatment, if HistoScanning-targeted biopsies improve the yield of positive tumour biopsies, interuser and interobserver variability, reproducibility of subsequent Histoscans, ease of use in clinical practice and the correlation of HistoScanning with pathological findings of prostate biopsies and radical prostatectomy specimens.

Study design

Prospective multicentre observational study.

Patients will visit the outpatient clinic for a transrectal computer-aided ultrasonography (Histoscanning) at 0, 3, 6, 12, 18 and 24 months. At 12 months patients will also receive two HistoScanning guided biopsies simultaneously with the scheduled systematic biopsies within the PRIAS study.

Study burden and risks

The visits for HistoScanning can be combined with the visits for the PRIAS-study. The HistoScanning should, from the patient*s perspective, be no different to a standard diagnostic transrectal ultrasonography. The benefit for the patient could be a more accurate biopsy sampling and therefore in case of a progressive cancer an earlier discovery.

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

• Male patient aged >= 18 years.
• Newly diagnosed patients participating in PRIAS or patients participating for 3 years.
• PRIAS has the following inclusion criteria:
o Histologically proven adenocarcinoma of the prostate
o Patient should be fit for curative treatment
o PSA-level at diagnosis <= 10 ng/mL
o PSA density (PSA D) less than 0,2
o Clinical stage T1C or T2
o Appropriate biopsy sampling
o Gleason score 3+3=6 (or less)
o One or 2 biopsy cores invaded with prostate cancer
o Participants must be willing to attend the follow-up visits
• Provides written Informed Consent and is willing and able to comply with protocol requirements.

Exclusion criteria

• Incapable of understanding the language in which the information for the patient is given.
• Patient who can not or do not want to be radiated or operated

• Previously treated for prostate cancer

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2009
Enrollment:	115
Type:	Actual

Ethics review

Approved WMO

Date:	13-08-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL27765.078.09