Comparisson of HistoScannnig guided prostate biopsy with systematic prostate biopsy in the detection of prostate cancer.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28683

Source
NTR

Brief title
HSGB

Health condition

Prostatic neoplasms, prostate biopsy, computer aided ultrasonography, Histoscanning.
Prostaatkanker, prostaatbiopsie, computer ondersteunde echografie.

Sponsors and support

Primary sponsor: Erasmus Medical Center, Department of Urology
Source(s) of monetary or material Support: Erasmus Medical Center, Department of Urology

Intervention

Outcome measures

Primary outcome

Binary variable in terms of benign or malignant.

Secondary outcome

1. Gleason score;

2. Proportion of positive biopsy cores.

Study description

Background summary

Rationale:

Biopsies are taken systematically from the prostate without an imaging technique that allows us to visualize areas suspicious of cancer. Various studies conducted have shown that up to 35% of all clinically significant prostate cancers are not detected by systematic biopsy. In this study we will evaluate the potential of HistoScanningTM guided biopsy to increase the detection rate of prostate cancer.

Objective:

The primary objective of this study is to compare HistoScanningTM guided prostate biopsy with systematic biopsy in the detection of prostate cancer in men candidate for a first or second biopsy procedure.

Study design:

Observational pilot study.

Study population:

Men ≥ 40 years old with a clinical suspicion of prostate cancer and candidate for a bioptic procedure. The study population comprises both candidates for a first bioptic exam and candidates for a second bioptic procedure having a previous negative result independently from the present study.

Study procedure:

Patients will receive a HistoScanning prior to the biopsy procedure. In case one or more lesions of ≥ 0.2 cm3 are seen with HistoScanning a maximum of 4 HistoScanning guided prostate biopsy cores are taken in addition to the standard systematic prostate biopsies (8, 10 or 12 biopsies, dependent on prostate volume).

Main study parameters/endpoints:

Number of standard and HistoScanning guided cores, number of positive standard and HistoScanning guided cores, length of standard and HistoScanning guided core, % of standard and HistoScanning guided core infiltrated with cancer, Gleason score of standard and HistoScanning guided biopsies, prostate volume, baseline PSA, PSA density, results of digital rectal examination (DRE), TRUS and HistoScanning analysis.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The HistoScanning procedure should, from the patient’s perspective, be no different from standard diagnostic transrectal ultrasonography. The systematic and HistoScanning guided biopsy will be performed in the same session, so no extra visit is required. A maximum of 4 HistoScanning guided biopsy cores will be performed in addition to the standard systematic biopsy. Accordingly the number of bioptic cores taken in this study will not exceed 16.

Study objective

In this study we will evalute the potention of HistoScanning guided biopsy to increase the detection rate of prostate cancer.

Study design

There will be no follow-up. Patients visit the clinic once for the combined systematic and guided biopsy procedure.

Intervention

There will be no intervention. Patients undergo systematic and guided biopsies (invasive measurement).

Contacts

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Eligibility criteria

Inclusion criteria

1. Male patient aged ≥ 40 years;

2. Patient with a clinical suspicion of prostate cancer and scheduled for first bioptic procedure or patient who already received one systematic biopsy procedure with negative results currently under follow-up procedure due to a persistent indication;

3. Provides written informed consent and is willing and able to comply with protocol requirements.

Exclusion criteria

1. A history of previous prostate surgery;

2. Clinically apparent prostatitis within one month of biopsy;

3. Active urinary tract infection;

4. Has received a bioptic procedure within 30 days before admission into this study;

5. Incapable of understanding the language in which the information for the patient is given.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-04-2010
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-05-2010
Application type:	First submission

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
NTR-new	NL2217
NTR-old	NTR2342
Other	METC Erasmus MC / CCMO : MEC-2010-007 / NL30800.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A