A pilot study to compare HistoScanning guided prostate biopsy with systematic biopsy in the detection of prostate cancer.

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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.

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

Summary

ID

NL-OMON34983

Source
ToetsingOnline

Brief title
HistoScanning guided prostate biopsy.

Condition

- Reproductive neoplasms male malignant and unspecified
- 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: Detection of prostate cancer, HistoScanning, Imaging technique, Prostate biopsy

Outcome measures

Primary outcome

The main endpoint for cancer detection is a binary variable in terms of benign

or malignant.

Secondary outcome

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.

Study description

Background summary

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.

Study 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. 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).

Study burden and risks

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.

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 >= 40 years.
• 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.
• Provides written informed consent and is willing and able to comply with protocol requirements.

Exclusion criteria

• A history of previous diagnosis of prostate cancer or prostate surgery.
• Clinically apparent prostatitis within one month of biopsy.
• Active urinary tract infection.
• Has received a bioptic procedure within 30 days before admission into this study.
• Incapable of understanding the language in which the information for the patient is given.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	07-05-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2010
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	NL30800.078.09