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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28683

Bron
NTR

Verkorte titel
HSGB

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Department of Urology
Overige ondersteuning: Erasmus Medical Center, Department of Urology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Binary variable in terms of benign or malignant.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-04-2010
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-05-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A