The biopsy-core yield of biopsy-core processing using traditional formalin jars versus the semi-automatic download using the SmartBx system.

Published: 18-08-2015
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To determine whether prostate biopsies processed with the SmartBX system result in more and better interpretable material.

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

Summary

ID

NL-OMON42577

Source
ToetsingOnline

Brief title
Biopsy core yield using the SmartBx system

Condition

- Reproductive neoplasms male malignant and unspecified

Synonym
Prostate Cancer prostate carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: KWF kankerfonds

Intervention

Keyword: biopsy, core, processing, prostate

Outcome measures

Primary outcome

loss of biopsy core length during processing (length on needle - length on

pathology slide) compared between the SmartBX system and the traditional method

of shaking the biopsy cores into formalin jars.

Secondary outcome

none

Study description

Background summary

In Patients with a clinical suspicion of prostate cancer, prostate biopsies are often required to confirm or reject the diagnosis. After taking the biopsy core, it is normally shaken from the biopsy needle into a formalin jar. This causes fragmentation of the cores, loss of material and the orientation of the specimen within the prostate is lost. The fragments must be removed from the jars, straightened, and put embedded in paraffin. This is a time consuming and therefore costly process. WIth the SmartBX system the biopsy specimen is downloaded from the biopsy needle in a cartridge with a special paper. This preserves all the biopsy material, reduces fragmentation and preserves the orientation of the specimen. The processing of the specimen requires less handling which saves time and money.

Study objective

To determine whether prostate biopsies processed with the SmartBX system result in more and better interpretable material.

Study design

In 60 patients, half the biopsies will be processed in the traditional way and half the biopsies with the SmartBX system. Randomization will determine which side of the prostate will be done with which method. The length of the biopsy

core is recorded on the biopsy needle with a camera. the length of the biopsy specimen is again measured on the final pathology slide used for interpretation. We then determine whether the cores processed with the SmartBX system suffer from more or less loss of length during processing.

Study burden and risks

No burden. The same amount of biopsy cores will be taken, from the normal locations using the same technique and equipment. normally all biopsies are shaken of the needle into a formalin jar. Now half of the biopsy cores are taken of the needle using the SmartBx system. The only risk to the patient is that the cores processed with the SmartBx end up being less well interpret-able. This is very unlikely based on previous research and our own experiences with the system. The ultimate consequence of un interpretable material would be that the participant would have to have half of the prostate biopsies (left or right lobe determined by randomization) retaken.

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

referred for prostate biopsies

Exclusion criteria

age below 18

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	The SmartBx tool aids in removing the biopsycore from the biopsy needle
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-08-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL52856.018.15