A European, Multi-Centre Study to Evaluate the Value of Real-Time Elastography in the Diagnosis of Prostate Carcinoma

Published: 19-08-2013
Last updated: 24-04-2024

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Renal and urinary tract neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON38888

Source
ToetsingOnline

Brief title
Multi-centre Prostate RTE Study

Condition

- Renal and urinary tract neoplasms malignant and unspecified

Synonym
Prostate adenocarcinoma, prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Stichting Cure for Cancer

Intervention

Keyword: Elastography, prostate biopsy, Prostate carcinoma, Ultrasound

Outcome measures

Primary outcome

See objective

Secondary outcome

See objective

Study description

Background summary

Elastography is an ultrasound imaging technique based on the concept that significant differences exist between elastic properties of benign and malignant tissue. It is able to detect the change in reflection of sound waves when manual compression is applied to the tissue.

In 2010 Aigner et al. compared elastography guided biopsies with 10 core systematic biopsies in 94 men with a low PSA (mean 3.2 ng/ml, range 1.3 to 4.0). PCa was found in 27 patients (28.7%). They showed that the detection rate of PCa per patient was comparable, in the elastography guided (21.3%) and in the systematic biopsies(19.1%). n the elastography group a sensitivity of 74% and specificity of 60% was found per patient. However with elastography significantly less biopsies were taken (158 versus 752).
In 2011 Kapoor et al. performed a similar study in 50 patients with a high PSA (mean 12.6 ng/ml, range 9.8 to 14.4) 5. PCa was found in 12 patients (24%). Per patient the sensitivity and specificity were 91.7% and 86.8% respectively. Per core sensitivity and specificity were 72.5% and 100% respectively.

The unicentric studies carried out so far have shown it is possible to view a significantly larger number of prostate carcinoma foci by conducting elastography guided biopsies when compared with TRUS-controlled biopsies. Furthermore, the increase in the detection rate of PCA cases thanks to the use of elastography guided biopsies was also demonstrated.

Study objective

The objective of this study is to record and evaluate an elastography guided biopsy used in routine clinical procedure and to validate its value with respect to improved prostate carcinoma visualisation and detection.

The intention is to represent the benefits of this method in terms of an increased hit rate when compared with a randomised "blind" biopsy. For this purpose, biopsies taken under conventional conditions using transrectal ultrasonography will be compared with biopsies which have been obtained using the elastography method. The aim is to identify to what extent real-time elastography can not only achieve an in-creased hit rate but also a more precise tumour classification (tumour stage, aggres-siveness of the tumour). If it is the case that, due to a diagnosed prostate carcinoma, the prostate must be removed, then the results from the biopsy will be compared with the histopathological examination of the specimen.

Hypothesis:
It is assumed that the use of an elastography-controlled biopsy will result in at least a 5% increase in the diagnosis of prostate carcinomas. This method should detect more prostate carcinomas than TRUS-controlled biopsies.

Study design

The patient has voluntarily opted to have a biopsy.
* During the course of the meeting with the physician, the patient will provide their consent to participate in the evaluation study (see participant information and consent).
* The examination will take place blinded and will be carried out by two examiners. First of all, examiner 1 will proceed with the elastography. and then leave the room.
* Examiner 2 then comes in and proceeds with the conventional ultrasound and consecutively the randomised 12 x biopsies.
* Then examiner 1 wil come in again and will perform the targeted sampling under elastography conditions.
* The elastography guided biopsy includes 4 biopsies: In each case, these are two biopsies from the two most conspicuous elastography areas.

Study burden and risks

Ultrasound is considered a safe diagnostic tool because of the use of non-ionizing radiation.

The risk of side-effects is not increased compared to the standars biopsies which the patient undergoes for routine clinical diagnosis next to this study.

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

Planned for prostate biopsy
Over 18years old
Signed informed consent

Exclusion criteria

- acute prostatitis of urinary tract infection
- had prostate biopsy within 30 days

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-08-2013
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	NL43763.018.13