Prostate volume measurement by the general practitioner

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In this research project it is investigated if abdominal ultrasound measurement of prostate volume performed by the GP is equivalent to the prostate volume measured by the transrectal ultrasound (TRUS) performed by the urologist. Also the effect on...

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

Summary

ID

NL-OMON41082

Source
ToetsingOnline

Brief title
Prostate volume measurement by GP

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: Stichting Urologisch Wetenschappelijk Onderzoek (SUWO)

Intervention

Keyword: Abdominal ultrasound, Prostate cancer risk calculator, Prostate volume measurement, Transrectal Ultrasound (TRUS)

Outcome measures

Primary outcome

The main endpoint is the difference in prostate volume measured by the GP

(abdominal) and the urologist (TRUS), and the effect of this difference on the

risk of PCa calculated with the prostate risk calculator.

Secondary outcome

Measurement of compliance of the GP and urologist to the risk calculator

advice.

Study description

Background summary

Risk stratification helps to better identify those men at risk for (potentially aggressive) PCa. The Erasmus MC has developed six risk calculators (www.prostaatwijzer.nl) to calculate for example the risk of having PCa detectable with prostate biopsy. Implementing the risk calculators in the daily practice of general practitioners (GP*s) and urologists may prevent many unnecessary prostate biopsies and overdiagnosis. Usually, most examinations of the prostate are performed by an urologist in the hospital. Enabling the GP to measure the prostate volume of a patient with an ultrasound himself, facilitates the use of more advanced risk calculators in the primary health care setting. Based on the results of PSA, digital rectal examination (DRE), and prostate volume a risk can be calculated of finding (a potentially aggressive) PCa at prostate biopsy. A strategy where the decision to biopsy is dependent on this risk will reduce the amount of biopsies and the diagnosis of low risk PCa. Currently prostate volume measurements (necessary for calculating the risk) are only performed by the urologist. Volume measurement by the GP may reduce referrals to the urologist.

Study objective

In this research project it is investigated if abdominal ultrasound measurement of prostate volume performed by the GP is equivalent to the prostate volume measured by the transrectal ultrasound (TRUS) performed by the urologist. Also the effect on the risk calculated by the prostate risk calculators (nr. 3 and nr. 4) will be investigated.

Study design

Prospective comparative clinical study, where the patient serves as its own control.

Study burden and risks

In normal clinical practice each patient will visit his GP once and the urologist once in case of an abnormal PSA. In between an extra visit to the GP or a telephone consultation for PSA result is normal.

During this study patients will undergo an extra abdominal measurement of the prostate volume at the GP. A total of 7 GP*s are included in this project but only 3 will be able to perform the abdominal ultrasound measurements. Some of the patients will have to make an extra visit to another GP for the prostate volume measurement. All patients will have to visit the urologist no matter what the results of the investigations at the GP are. Besides the extra visits, the additional abdominal ultrasound does not pose any risk for the participant.

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

- men who have their PSA tested by the GP
- 50-70 years
- willing to have their prostate volume measured twice (the first time abdominally by a GP and the second time rectally by an urologist of the Prostaatcentrum zuidwest Nederland)
- signed informed consent

Exclusion criteria

- Prostate cancer in medical history

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	12-09-2014
Enrollment:	116
Type:	Actual

Ethics review

Approved WMO Date:	14-05-2014
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	NL47803.078.14