Prostate cancer: which patients need (repeated) prostate biopsies and how many biopsies do they need?

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28233

Source
NTR

Brief title
8 versus 12 prostate biopsies

Health condition

Prostate Cancer

Sponsors and support

Primary sponsor: AMC, department of Urology, Amsterdam, the Netherlands
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

- How many prostate cancers are found using a 12-biopsy protocol compared to an 8-biopsy protocol.

- How many cancers are found in repeated biopsies after using a 12-biopsy protocol compared to an 8-biopsy protocol

- What % of cancers is found in the transition zone only in repeated biopsies after using a 12-biopsy protocol compared to an 8-biopsy protocol

Secondary outcome

- How do the primary outcomes relate to patient characterisics such as age, PSA, PSA-ratio, complexed PSA, symptoms.

- How many more complications occur in a 12 biopsy-protocol compared to an 8- biopsy protocol.

Study description

Background summary

Patients scheduled for prostate biopsies were randomized in the group of 8 ultrasound-guided transrectal biopsies or in the group with 12 ultrasound-guided transrectal biopsies to determine the incremental detection and complication rate using the two biopsy protocols and in repeated biopsies and to identify subgoups in which repeat biopsies can be safely omitted.

Study objective

More early stage cancers (T1,T2) will be found by increasing the number of biopsies per session and lowering the PSA cutt off values.

Study design

2 years

Intervention

All biopsies will be taken in the left lateral decubitus position.

Group 1:
8 ultrasound-guided transrectal biopsies, laterally aimed in the peripheral zone: one from the apex, two from the middle and one from the base on each side.

Group 2:
12 biopsies including 6 parasaggital cores and 6 lateral cores, one from the apex, one from

the middle and one from the base on each side of the prostate.

Contacts

Public
Academic medical Center (AMC) Department of Urology
P.O. Box 22660
S.A. Zaaijer
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5666030
Scientific
Academic medical Center (AMC) Department of Urology
P.O. Box 22660
S.A. Zaaijer
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5666030

Eligibility criteria

Inclusion criteria

1. Age < 50 and PSA > 1,24 ng/ml

2. Age > 49 < 60 and PSA > 2,24 ng/ml

3. Age > 59 <70 and PSA > 2,24 ng/ml

4. Age >69 and PSA > 3,24 ng/ml

5. Abnormal DRE

6. Abnormal TRUS

Exclusion criteria

1. Age < 18

2. Proven prostate cancer

3. Clinical prostatitis < 1 month ago

4. Acute urinary retention < 1 month ago

5. PSA altering medicine (finasteride, dutasteride) used in the last 6 months

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-10-2004
Enrollment:	400
Type:	Actual

Ethics review

Positive opinion

Date:	07-07-2008
Application type:	First submission

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
NTR-new	NL1319
NTR-old	NTR1368
Other	MEC : 04/079
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A