The BIOPRES-trial; Transrectal Biopsies of the Prostate: End versus Side firing

Published: 21-10-2009
Last updated: 04-05-2024

To investigate the difference between side and end-firing in transrectal prostate needle biopsies in terms of qualitative and quantitative prostate cancer detection.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Interventional

Summary

ID

NL-OMON32971

Source
ToetsingOnline

Brief title
BIOPRES

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC

Synonym
malignancy of the prostate, prostate cancer

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Amphia academie en de maatschap urologie van het Amphia ziekenhuis

Intervention

Keyword: biopsy, cancer, prostate, transrectal ultrasound

Outcome measures

Primary outcome

The primary endpoint is the prostate cancer detection rate

Secondary outcome

secondary endpoints are the number of cores invaded with prostate cancer,

nomogram for indolent cancer-score, Gleason score, complications and biopsy

length

Study description

Background summary

Research towards the efficacy of transrectal prostate biopsies has predominantly focused on the amount of biopsy cores. However, variation in the angle of entrance of the biopsy gun has been less studied. It is believed that obtaining biopsy cores by end firing will improve the efficacy, because of an improved sampling of the apical region.

Study objective

To investigate the difference between side and end-firing in transrectal prostate needle biopsies in terms of qualitative and quantitative prostate cancer detection.

Study design

all men with a prostate biopsy in a representative, Dutch, general hospital with six participating urologists and two residents will be subjected to a randomized controlled, single blind, single center, diagnostics trial. Men will be randomized for a biopsy using an end-firing or a side-firing probe.

Intervention

A transrectal biopsy of the prostate with the use of an end-firing probe versus the use of a side-firing probe.

Study burden and risks

there are no risks other than the risks for a prostate biopsy outside this study.

Contacts

Public
Amphia Ziekenhuis

Postbus 90157
4800 RL Breda
NL
Scientific
Amphia Ziekenhuis

Postbus 90157
4800 RL Breda
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• All prostate biopsies
• PSA and DRE performed in advance of the biopsy

• Informed consent

Exclusion criteria

none

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2009
Enrollment:	800
Type:	Actual

Medical products/devices used

Generic name:	transrectal ultrasound
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	21-10-2009
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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
ClinicalTrials.gov	NCT00851292
CCMO	NL28086.101.09