Circulating PSA-containing macrophages: a tool to distinguish indolent from aggressive prostate cancer? A pilot study.

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To apply a novel blood assay to 150 patients undergoing a radical prostatectomy in order to assess whether this test can accurately identify indolent cancers and thereby prevent unnecessary treatments. To increase the accuracy of the flow cytometric...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Reproductive and genitourinary neoplasms gender unspecified NEC
Study type	Observational invasive

Summary

ID

NL-OMON33803

Source
ToetsingOnline

Brief title
PSA in macrophages

Condition

- Reproductive and genitourinary neoplasms gender unspecified NEC
- 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: Ministerie van OC&W,BD Biosciences

Intervention

Keyword: Multi-parameter flow cytometric test, Prostate Cancer, PSA-positive macrophages, Tumour stage

Outcome measures

Primary outcome

The difference in the number of activated PSA positive macrophages

(preoperatively) between patients with significant and insignificant cancers

(insignificant defined as < 0.5 ml of cancer, no Gleason pattern 4 or 5, no

extraprostatic extension, no seminal vesicle invasion, no lymph node metastasis

and absence of positive surgical margins).

Secondary outcome

- The difference in the number of activated PSA positive macrophages (at 1

week, 6 weeks and 6 months postoperatively) between patients with significant

and insignificant cancers.

- The difference in the number of activated PSA positive macrophages

(preoperatively, or at 1 week, 6 weeks, 6 months postoperatively) between

patients with biochemical recurrence (serum PSA at 3 months and 1 year

postoperatively > 0.2 ng/ml)

Study description

Background summary

Prostate cancer is the most prevalent malignancy in males in the Western world and the second leading cause of male cancer death. The number of diagnosed prostate cancers is rising due to PSA (prostate specific antigen) testing in the population. The majority of the detected cancers will not effect survival. However, at present these indolent cancers cannot be identified accurately, which leads to unnecessary treatment in 30-50% of cases (radical prostatectomy or radiotherapy). Apart from health care costs, this treatment is associated with important side effects (erectile dysfunction and incontinence). Consequently, there is an urgent need to improve the selection of patients for invasive therapies.

Recently a multi-parameter flow cytometric test has been developed which detects circulating macrophages with intracellular PSA, which are assumed to be tissue macrophages derived from the prostate. A strong correlation has been found between the number of circulating PSA-positive macrophages and prostate cancer tumour stage.

Study objective

To apply a novel blood assay to 150 patients undergoing a radical prostatectomy in order to assess whether this test can accurately identify indolent cancers and thereby prevent unnecessary treatments. To increase the accuracy of the flow cytometric assay, we aim to incorporate additional antibodies against tumor-specific proteins.

Study design

This study is a prospective, invasive, observational study.

Study burden and risks

The burden for the patients exists of taking a total of 8 blood samples during 4 blood withdrawals. 3 times the blood will be taken during a regular blood withdrawal, for 1 blood withdrawal an extra puncture will take place. The burden and risks are thus minimal.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040

3000 CA Rotterdam
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Postbus 2040
3000 CA Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Men >= 18 years
- Histological confirmed adenocarcinoma of the prostate
- Localized prostate cancer
- Scheduled for radical prostatectomy
- Given informed consent

Exclusion criteria

- Metastatic disease
- Patient not able to understand the patient information

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-07-2009
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	14-05-2009
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	NL25782.078.08