Selenium and Prostate Cancer; Clinical Trial on Availability to Prostate Tissue and Effects on Gene Expression.

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The aim of this study is to get insight into bioavailability of selenium in prostate tissue and changes of gene expression profiles that might be responsible for selenium-induced chemoprevention. To meet this objective, the relationship between...

Ethical review	Approved WMO
Status	Pending
Health condition type	Reproductive neoplasms male malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON30578

Source
ToetsingOnline

Brief title
Selenium and Prostate Cancer

Condition

- Reproductive neoplasms male malignant and unspecified
- Prostatic disorders (excl infections and inflammations)

Synonym
prostate cancer, prostatic neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Wereld Kanker Onderzoek Fonds (WCRF;NL

en WCRF;UK)

Intervention

Keyword: Gene expression, Intervention trial, Prostatic neoplasms, Selenium

Outcome measures

Primary outcome

Levels of selenium in prostate tissue and changes in prostate gene expression profiles of participants supplemented with selenium or placebo, compared before and after the short intervention period, will be considered as the main parameters of the present study.

Secondary outcome

Besides gene expression profiles in prostate tissue, also gene expression profiles of peripheral mononuclear cells, levels of selenium in blood and toenails and blood flow and permeability of blood vessels of prostate tissue will be analyzed to examine the biological effects of selenium supplementation.

Study description

Background summary

Prostate cancer is a frequently observed malignancy in men, especially in elderly men. Besides diagnosis and treatment, also prevention of prostate cancer is an important point of interest to reduce the incidence and mortality of prostate cancer. Selenium is considered to be a promising chemopreventive agent for prostate cancer. Exact mechanisms of chemoprevention by selenium are not fully understood, however it is supposed that selenium (among other effects) directly affects gene expression in the prostate.

Study objective

The aim of this study is to get insight into bioavailability of selenium in prostate tissue and changes of gene expression profiles that might be

responsible for selenium-induced chemoprevention. To meet this objective, the relationship between dietary selenium intake and changes in gene expression profiles, tissue selenium levels and blood flow in prostate tissue will be examined.

Study design

The present study is designed as a double blind, randomized and placebo-controlled intervention trial. Baseline blood samples, questionnaires, MRI images and surgical specimens will be collected to examine effects of selenium supplementation.

Intervention

Participants will receive (dietary supplement) 300 ug selenium / day or a placebo. Selenium will be provided in the form of selenized yeast tablets (SelenoPrecise, Pharma Nord) during 5 weeks prior to radical prostatectomy.

Study burden and risks

Risk and burden associated with the present study will be comparable to the standard medical treatment. The participants will be asked to fill in questionnaires concerning personal characteristics, medical history and dietary habits. Participants will take dietary supplements or a placebo for a total period of 5 weeks, and will have two additional prostate biopsies and one additional MRI scan. Other procedures related to the participant will be according to the normal protocol of the department of Urology or Radiology.

Contacts

Public
Wageningen Universiteit

Postbus 8129
6700 EV Wageningen
Nederland
Scientific
Wageningen Universiteit

Postbus 8129
6700 EV Wageningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male
Caucasian ethnicity
Biopsy-proven prostate cancer
Scheduled for radical prostatectomy

Exclusion criteria

Adjuvant therapy for prostate cancer (e.g. HIFU, hormonal therapy)
Use of dietary supplements
Previously or concurrent diagnosed with cancer (other than prostate cancer)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	60
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NCT00446901
CCMO	NL14694.091.07