Lycopene and Vitamin E in men with minimal prostate cancer and rising PSA after radical prostatectomy. A double blind randomised placebo controlled cross-over study.

No registrations found.

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

Summary

ID

NL-OMON25453

Source
NTR

Brief title
BASF dietary study

Health condition

Minimal prostate cancer and rising PSA after radical prostatectomy.

Sponsors and support

Primary sponsor: BASF Aktiengesellschaft.

Intervention

Outcome measures

Primary outcome

Slope of the regression line through all two-weekly PSA measurements.

Secondary outcome

Plasma levels of testosterone, estradiol, DHEA, DHT, and SHBG, and IGF-1 during the intervention as compared to placebo.

Study description

Background summary

The goal of this protocol is to show an effect of a dietary supplement on PSA progression. This will be measured by the impact of the dietary supplement on the slope of a documented PSA rise, which is translatable into an effect on PSA doubling time. This approach is considered by the study group as the closest approximation of a tertiary prevention study, which is at this moment clinically feasible.
Extra safeguards will be filled in by run-in and washout periods, as well as by conducting animal experimental studies on human prostate cancer lines in nude mice.
The present protocol should produce evidence that may lead to the justification of more extensive studies that would more definitely establish the value of dietary intervention with supplements.

Study objective

A combination of Lycopene and Vitamin E decreases PSA progression.

Study design

N/A

Intervention

Lycopene 15 mg and Vitamin E 400 IU each day during 12 weeks versus placebo. After a washout period cross-over will take place.

Contacts

Public
Erasmus Medical Center, Department of Urology,
P.O. Box 2040
F.H. Schröder

Dr. Molewaterplein 40

Rotterdam 3000 CA
The Netherlands
+31 (0)10 4634328
Scientific
Erasmus Medical Center, Department of Urology,
P.O. Box 2040
F.H. Schröder
Dr. Molewaterplein 40

Rotterdam 3000 CA
The Netherlands
+31 (0)10 4634328

Eligibility criteria

Inclusion criteria

1. Status after radical prostatectomy with potential curative intent;

2. Rising PSA;

3. Life expectancy >= 12 months;

4. Age >= 18 years.

Exclusion criteria

1. Current hormone therapy or hormone therapy during previous 12 months;

2. Orchidectomy;

3. Chemotherapy, radiotherapy or TURP prior to study resulting in PSA decrease that is currently ongoing.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-01-2003
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion

Date:	22-08-2005
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	NL95

Register	ID
NTR-old	NTR126
Other	: A300205
ISRCTN	ISRCTN02859773

Study results

Summary results

Schroder FH, Roobol MJ, Boeve ER, de Mutsert R, Zuijdgeest-van Leeuwen SD, Kersten I, Wildhagen MF, van Helvoort A.
Randomized, double-blind, placebo-controlled crossover study in men with prostate cancer and rising PSA: effectiveness of a dietary supplement.
Eur Urol. 2005 Dec;48(6):922-30; discussion 930-1. Epub 2005 Oct 17.