# Lycopene and vitamin E in men with minimal prostate cancer and rising prostate specific antigen after radical prostatectomy: a double blind randomised placebo controlled cross-over study

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
20/12/2005		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
20/12/2005		[X] Results		
Last Edited	Condition category	[] Individual participant data		
13/11/2008	Cancer			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

EudraCT/CTIS number

**IRAS** number

## ClinicalTrials.gov number

## Secondary identifying numbers

A300205; NTR126

# Study information

#### Scientific Title

## Acronym

BASF dietary study

## **Study objectives**

The goal of this protocol is to show an effect of a dietary supplement on prostate specific antigen (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.

## Hypothesis:

A combination of Lycopene and Vitamin E decreases PSA progression.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

Received from the local medical ethics committee

# Study design

Randomised, placebo controlled, crossover group, double blinded multicentre trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Prostate cancer

## **Interventions**

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

## Intervention Type

Supplement

#### Phase

**Not Specified** 

## Drug/device/biological/vaccine name(s)

Lycopene, Vitamin E

## Primary outcome measure

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

## Secondary outcome measures

Plasma levels of testosterone, oestradiol, dehydroepiandrosterone (DHEA), dihydrotestosterone (DHT), and sex hormone-binding globulin (SHBG), and insulin-like growth factor 1 (IGF-1) during the intervention as compared to placebo.

## Overall study start date

27/01/2003

# Completion date

30/06/2006

# **Eligibility**

# Key inclusion criteria

- 1. Status after radical prostatectomy with potential curative intent
- 2. Rising PSA
- 3. Life expectancy more than or equal to 12 months
- 4. Age more than or equal to 18 years

# Participant type(s)

Patient

# Age group

Adult

# Lower age limit

18 Years

## Sex

## Target number of participants

80

## Key exclusion criteria

- 1. Current hormone therapy or hormone therapy during previous 12 months
- 2. Orchidectomy
- 3. Chemotherapy, radiotherapy or transurethral resection of the prostate (TURP) prior to study resulting in PSA decrease that is currently ongoing

## Date of first enrolment

27/01/2003

## Date of final enrolment

30/06/2006

# Locations

## Countries of recruitment

Netherlands

# Study participating centre Department of Urology

Rotterdam Netherlands 3000 CA

# Sponsor information

## Organisation

BASF Aktiengesellschaft (Germany)

## Sponsor details

Carl-Bosch-Str. 38 Ludwigshafen Germany DE-67063

## Sponsor type

Industry

#### Website

http://corporate.basf.com/de/?id=V00-MtkCyA4GZbcp.sn

## **ROR**

https://ror.org/01q8f6705

# Funder(s)

## Funder type

Not defined

## Funder Name

Not provided at time of registration

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/12/2005		Yes	No