

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 20/12/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 13/11/2008	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

Key exclusion criteria

1. Current hormone therapy or hormone therapy during previous 12 months
2. Orchiectomy
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)

ROR

<https://ror.org/01q8f6705>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

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