ISRCTN02859773 https://doi.org/10.1186/ISRCTN02859773

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

Registration date
20/12/2005

Overall study status
Completed

Last Edited
13/11/2008

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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

Male

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