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.

Gepubliceerd: 22-08-2005 Laatst bijgewerkt: 18-08-2022

A combination of Lycopene and Vitamin E decreases PSA progression.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25453

Bron
NTR

Verkorte titel
BASF dietary study

Aandoening

Minimal prostate cancer and rising PSA after radical prostatectomy.

Ondersteuning

Primaire sponsor: BASF Aktiengesellschaft.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

A combination of Lycopene and Vitamin E decreases PSA progression.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Status after radical prostatectomy with potential curative intent;

2. Rising PSA;

3. Life expectancy >= 12 months;

4. Age >= 18 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	27-01-2003
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	22-08-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL95
NTR-old	NTR126
Ander register	: A300205
ISRCTN	ISRCTN02859773

Resultaten

Samenvatting resultaten
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.