AVOCAT study

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To evaluate the difference in percentages of patients with PSA progression treated with either bicalutamide 150 mg/day in monotherapy or bicalutamide 150 mg/day + dutasteride 0.5 mg/day after 3 years of follow-up in patients with locally advanced or...

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

Samenvatting

ID

NL-OMON26811

Bron
NTR

Verkorte titel
AVOCAT study

Aandoening

Locally advanced or metastatic carcinoma of the prostate.

Ondersteuning

Primaire sponsor: STIWU: Stichting ter bevordering van het Wetenschappelijk Urologisch onderzoek
(Foundation for the stimulation of Scientific Urological Research.)
Overige ondersteuning: N/A

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PSA progression after 3 years of study treatment

Toelichting onderzoek

Achtergrond van het onderzoek

Patients will be randomised for treatment with either:

1. Antiandrogen monotherapy: bicalutamide 150 mg taken orally, three tablets of 50 mg bicalutamide daily without interruption or

2. Bicalutamide 150 mg taken orally, three tablets of 50 mg bicalutamide daily plusDutasteride 0.5 mg, 1 capsule, once daily.

It is reasonable to consider that the combination of the 5-alpha-reductase inhibitor, dutasteride, and a pure antiandrogen such as bicalutamide should provide an effective form of maximal androgen blockade (MAB). Dutasteride decreases intraprostatic levels of 5-alpha dihydrotestosterone (DHT), and the antiandrogen would restrain the biological action of the residual DHT by interfering with its association with androgen receptor. This form of MAB should sustain the concentration of testosterone in plasma, thereby maintaining sexual function and reasonable quality of life. In earlier studies with locally advanced prostate cancer patients, finasteride provided additional intraprostatic androgen blockade to flutamide, as measured by additional PSA suppression and a median protocol treatment failure-free survival of 29,9 months, a median castration-free survival of 37 months and an overall survival of 65 % after 5 years. With bicalutamide 150 mg therapy PSA progression is expected in 17-20 % of the patients with locally advanced prostate cancer with 3-4 years of follow up. With the combination finasteride and flutamide therapy PSA progression is expected in 40 % of the patients with locally advanced or M1 prostate cancer with 3 years of follow up.

In order to investigate if the combination of dutasteride and bicalutamide is more effective than bicalutamide therapy alone, this randomized multicenter phase III clinical trial of patients with locally advanced or metastatic cancer of the prostate is proposed.

Doel van het onderzoek

To evaluate the difference in percentages of patients with PSA progression treated with either bicalutamide 150 mg/day in monotherapy or bicalutamide 150 mg/day + dutasteride 0.5 mg/day after 3 years of follow-up in patients with locally advanced or metastatic prostate cancer.

Onderzoeksproduct en/of interventie

Group 1 will be hormonally treated with bicalutamide 150 mg/day monotherapy.

Group 2 will be hormonally treated with bicalutamide 150 mg/day + 0.5 mg dutasteride/day

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients aged 18 years and above

2. Patients with histologically proven prostate cancer.

3. Patients with locally advanced carcinoma of the prostate (T3-4, N0-x) or (T0-x, N1-3; N category should be confirmed histologically or cytologically) or metastatic carcinoma of the prostate (M1).

4. Patients with a high (> 10 ng/ml) PSA level at baseline.

5. Written informed consent to participate in the study.

6. Life expectancy is at least 12 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients simultaneously participating in another study.

2. Previous or concurrent chemotherapy, 5-alpha reductase inhibitor therapy or hormonal therapy specifically for the treatment of prostate cancer other than temporary neo-adjuvant hormonal therapy administered longer than 1 year prior to study entry.

3. Development of another invasive neoplastic disease during the previous 5 years, or concomitant presence of another invasive neoplastic disease, except basal cell carcinoma or squamous cell carcinoma of the skin.

4. Patients with a history or presence of hepatic or renal disease or other condition known to interfere with metabolism or excretion of drugs.

5. Patients with a history of alcohol or drug abuse.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2006
Aantal proefpersonen:	324
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2006
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	NL752
NTR-old	NTR763
Ander register	: N/A
ISRCTN	ISRCTN47114653

Resultaten

Samenvatting resultaten
N/A