AVOCAT study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26811

Source
NTR

Brief title
AVOCAT study

Health condition

Locally advanced or metastatic carcinoma of the prostate.

Sponsors and support

Primary sponsor: STIWU: Stichting ter bevordering van het Wetenschappelijk Urologisch onderzoek
(Foundation for the stimulation of Scientific Urological Research.)
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

PSA progression after 3 years of study treatment

Secondary outcome

1. Quality of life

2. Performance Status

3. Disease progression

4. Survival

5. Nature and number of Adverse Events

Study description

Background summary

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.

Study objective

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2006
Enrollment:	324
Type:	Anticipated

Ethics review

Positive opinion

Date:	06-09-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL752
NTR-old	NTR763
Other	: N/A
ISRCTN	ISRCTN47114653

Study results

Summary results
N/A