

An open-label, prospective, comparative trial to assess prostate specific antigen progression on bicalutamide monotherapy versus bicalutamide and dutasteride therapy in patients with advanced and/or metastatic carcinoma of the prostate

Submission date 22/11/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/11/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/01/2020	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

Study information

Scientific Title

An open-label, prospective, comparative trial to assess prostate specific antigen progression on bicalutamide monotherapy versus bicalutamide and dutasteride therapy in patients with advanced and/or metastatic carcinoma of the prostate

Acronym

AVOCAT study

Study objectives

To evaluate the difference in percentages of patients with Prostate Specific Antigen (PSA) progression treated with either bicalutamide 150 mg/day in monotherapy or bicalutamide 150 mg/day and dutasteride 0.5 mg/day after three years of follow-up in patients with locally advanced or metastatic prostate cancer.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Committee Human Research region Arnhem-Nijmegen (The Netherlands)

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prostate Cancer

Interventions

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

Group two will be hormonally treated with bicalutamide 150 mg/day and 0.5 mg dutasteride/day.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bicalutamide and dutasteride

Primary outcome(s)

PSA progression after three years of study treatment.

Key secondary outcome(s)

1. Quality of life
2. Performance Status
3. Disease progression
4. Survival
5. Nature and number of Adverse Events (AEs)

Completion date

31/03/2012

Eligibility**Key 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 (more than 10 ng/ml) PSA level at baseline
5. Written informed consent to participate in the study
6. Life expectancy is at least 12 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Male

Total final enrolment

150

Key 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 one year prior to study entry
3. Development of another invasive neoplastic disease during the previous five 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

Date of first enrolment

01/03/2006

Date of final enrolment

31/03/2012

Locations

Countries of recruitment

Netherlands

Study participating centre

CuraTrial

Arnhem

Netherlands

6803 AA

Sponsor information

Organisation

Foundation for the Promotion of Urological Scientific Research (STIWU) (The Netherlands)

Funder(s)

Funder type

Research organisation

Funder Name

Foundation for the Promotion of Urological Scientific Research (Stichting ter bevordering van het Wetenschappelijk Urologisch onderzoek [STIWU]) (The Netherlands)

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	17/05/2016	24/01/2020	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes