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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

Registration date
22/11/2006

Overall study status
Completed

Last Edited
24/01/2020

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

Study website
http://www.curatrial.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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)

Study design
Randomised controlled 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
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 measure
PSA progression after three years of study treatment.

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

Overall study start date
01/03/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
324

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)

Sponsor details
P.O. Box 9101
Nijmegen
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6500 HB

Sponsor type
Research organisation

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

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	17/05/2016	24/01/2020	Yes	No