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	Recruitment status No longer recruiting	Prospectively registered		
22/11/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/11/2006	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
24/01/2020	Cancer			

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.curatrial.com

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 Netherlands 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