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# A Multicentre Randomised and Comparative Trial to Assess the Tolerance, Efficacy and Pharmacokinetics of Escalating Doses of Casodex Versus Castration in the Treatment of Advanced Carcinoma of the Prostate

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|---|---|---|
| **Submission date**<br>19/08/2002 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>19/08/2002 | **Overall study status**<br>Completed | |
| **Last Edited**<br>29/10/2019 | **Condition category**<br>Cancer | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
ZEN7054IL/09

# Study information

### Scientific Title
A Multicentre Randomised and Comparative Trial to Assess the Tolerance, Efficacy and Pharmacokinetics of Escalating Doses of Casodex Versus Castration in the Treatment of Advanced Carcinoma of the Prostate

### Study objectives
Not provided at time of registration

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Not provided at time of registration

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Prostate cancer

### Interventions
1. Group A: Castration, medical or surgical
2. Group B: Casodex (bicalutamide) taken orally. Cohorts of patients were recruited sequentially, into each arm of the randomised stages, to determine the maximum well tolerated dose. The first cohort of patients received 300 mg Casodex, then patients were randomised to 300 mg Casodex versus castration, then 450 mg Casodex versus castration, then 600 mg Casodex versus 450 mg Casodex versus castration. The trial was stopped at 600 mg Casodex.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Casodex

### Primary outcome measure
Not provided at time of registration

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/01/1995

### Completion date
11/09/1996

## Eligibility

### Key inclusion criteria
1. Histologically/cytologically confirmed metastatic or locally advanced (T3 or T4) prostate carcinoma. Confirmed within the last month
2. Life expectancy of more than 3 months
3. Prostate specific antigen (PSA) of at least five-times upper limit of normal reference range
4. Evaluable disease and fit to receive any of the treatment options
5. No previous or concurrent systemic therapy for prostate cancer
6. No radiotherapy to the prostate within the 3 months prior to entry into the trial
7. No previous medical history of another malignancy within the past 5 years
8. Adequate cardiac, renal and hepatic function
9. Eastern Cooperative Oncology Group (ECOG) performance 3 or 4

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Male

### Target number of participants
Not provided at time of registration

### Total final enrolment
248

### Key exclusion criteria
Not provided at time of registration

**Date of first enrolment**
01/01/1995

**Date of final enrolment**
11/09/1996

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**UKCCCR Register Co-ordinator**
London
United Kingdom
NW1 2DA

# Sponsor information

**Organisation**
AstraZeneca Clinical Research Group (UK)

**Sponsor details**
10 Logie Mill
Beaverbank Office Park
Lovie Green Road
Edinburgh
United Kingdom
EH7 4HG

**Sponsor type**
Industry

**Website**
http://www.astrazeneca.co.uk

**ROR**
https://ror.org/04r9x1a08

# Funder(s)

**Funder type**
Industry

**Funder Name**
AstraZeneca Pharmaceuticals

# 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 | 01/09/2006 | 29/10/2019 | Yes | No |