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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

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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Male

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
United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
AstraZeneca Clinical Research Group (UK)

ROR
https://ror.org/04r9x1a08

Funder(s)

Funder type
Industry

Funder Name
AstraZeneca Pharmaceuticals

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