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A Study to Compare the Effect of Two Blinded Doses of Casodex (ICI 176,334 100 mg and 150 mg daily) and 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 21/01/2019	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr - -

Contact details
UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CASODEX 0307

Study information

Scientific Title
A Study to Compare the Effect of Two Blinded Doses of Casodex (ICI 176,334 100 mg and 150 mg daily) and 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

Interventions
STAGE I PATIENTS: Patients are randomised to either:
1. Casodex 100 mg
2. Casodex 150 mg
3. Castration

STAGE II PATIENTS: Patients are randomised to either:
1. Casodex 150 mg
2. Castration

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
01/01/1990

Completion date
30/06/1993

Eligibility

Key inclusion criteria
1. Locally advanced stage T3 or T4 carcinoma of the prostate with prostate-specific antigen times five the upper limit of normal or metastatic disease
2. Gleason grade 2-10
3. Evaluable disease
4. Fit to receive treatment

Participant type(s)
Patient

Age group
Not Specified

Sex
Male

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1990

Date of final enrolment
30/06/1993

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 (UK)

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	01/03/1998	21/01/2019	Yes	No