

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
Registration date 19/08/2002	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 21/01/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

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

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 (UK)

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