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	Recruitment status No longer recruiting	Prospectively registered		
19/08/2002		☐ Protocol		
Registration date 19/08/2002	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
21/01/2019	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

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 ma
- 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