A Multi-Centre, Randomised, Double Blind. Placebo Controlled Trial to Investigate the Effect of Bicalutamide (Casodex) 150mg on the Pharmacokinetics of Midazolam in Prostate Cancer Patients

	Prospectively registered
No longer recruiting	☐ Protocol
Overall study status	Statistical analysis plan
Completed	Results
Condition category	Individual participant data
Cancer	Record updated in last year
	Completed Condition category

Plain English summary of protocolNot 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

ZEN7054IL/29

Study information

Scientific Title

A Multi-Centre, Randomised, Double Blind. Placebo Controlled Trial to Investigate the Effect of Bicalutamide (Casodex) 150mg on the Pharmacokinetics of Midazolam in Prostate Cancer Patients

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)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

Patients are randomised to receive:

- 1. Treatment A: Bicalutamide 150 mg daily for 35 days plus three oral doses of midazolam 7.5 mg on days 1, 10 and 35.
- 2. Treatment B: Oral placebo daily for 35 days plus three oral doses of midazolam 7.5 mg on days 1, 10 and 35.

NB Active treatment Bicalutamide or placebo was only taken for 28 days (Day 8-35).

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bicalutamide (Casodex), Midazolam

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/01/1997

Completion date

06/02/1998

Eligibility

Key inclusion criteria

- 1. Histologically or cytologically confirmed prostate cancer
- 2. If surgically orchiectomised following 1 month depot of leutenizing hormone releasing hormone (LHRH) analogue therapy, at least 42 days must elapse from the end of the therapy before entry into the trial.
- 3. Adequate liver function
- 4. Not currently receiving drugs which may effect treatment

Participant type(s)

Patient

Age group

Not Specified

Sex

Male

Target number of participants

Not provided at time of registration

Key exclusion criteria

Patients are excluded if treated with 3 monthly LHRH analogue depots.

Date of first enrolment

01/01/1997

Date of final enrolment

06/02/1998

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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration