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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

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 09/12/2019	**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

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
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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