ISRCTN76165153 https://doi.org/10.1186/ISRCTN76165153

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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Male

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
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