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A pilot study to assess flutamide monotherapy compared With maximal androgen blockade in metastatic prostate cancer

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 29/10/2019	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SCTO46

Study information

Scientific Title
A pilot study to assess flutamide monotherapy compared With maximal androgen blockade in metastatic prostate cancer

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
1. Group A: Oral flutamide 250 mg three times daily
2. Group B: Oral flutamide 250 mg three times daily plus either orchidectomy or the lutenizing hormone releasing hormone (LHRH) analogue Zoladex (goserelin acetate). Zoladex is given by monthly injection at the dosage recommended by the manufacturer

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Flutamide, goserelin acetate

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/1994

Completion date
30/09/1996

Eligibility

Key inclusion criteria
1. Histologically confirmed prostate carcinoma
2. Skeletal metastases on bone scan, with radiological conformation if appropriate, or typical sclerotic metastases on X-ray
3. Life expectancy >6 months
4. Suitable for treatment by any of the study therapies
5. No previous hormonal therapy
6. Not currently receiving corticosteroids, spironolactone or aminoglutethamide
7. Adequate renal and hepatic function

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
01/01/1994

Date of final enrolment
30/09/1996

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Schering-Plough Ltd (UK)

Sponsor details
Schering-Plough House
Shire Park
Welwyn Garden City
United Kingdom
AL7 1TW

Sponsor type
Industry

ROR
https://ror.org/00148fb49

Funder(s)

Funder type
Industry

Funder Name
Schering-Plough Ltd (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