

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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

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

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Schering-Plough Ltd (UK)

ROR

<https://ror.org/00148fb49>

Funder(s)

Funder type

Industry

Funder Name

Schering-Plough Ltd (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration