

A prospective study to compare immediate with deferred treatment in advanced, localised and asymptomatic metastatic newly diagnosed prostatic carcinoma

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 15/11/2019	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

PR03

Study information

Scientific Title

A prospective study to compare immediate with deferred treatment in advanced, localised and asymptomatic metastatic newly diagnosed prostatic carcinoma

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. Immediate Group: Total or subcapsular orchidectomy or administration of a Lutenizing Hormone Releasing Hormone (LHRH) analogue. Suggested LHRH analogues are goserelin acetate (Zoladex) 3.6 mg monthly or leuprorelin (Prostap SR) 3.75 mg monthly. LHRH treatment to start within 6 weeks of randomisation.

2. Deferred Group: No hormone treatment until disease progression. The original protocol specified orchidectomy only as the method of androgen deprivation. The protocol was later modified to allow the use of LHRH analogues.

Intervention Type

Mixed

Primary outcome(s)

Not provided at time of registration.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

01/08/2005

Eligibility

Key inclusion criteria

1. Histologically proven adenocarcinoma of the prostate
2. Stage T2-T4 M0 or T1-T4 M1 (provided metastases are asymptomatic)
3. World Health Organisation (WHO) performance status 0-2
4. Life expectancy of >1 year
5. No previous or coexisting non prostatic malignancy except basal cell carcinoma
6. No previous treatment for prostatic carcinoma other than transurethral resection (TUR)
7. Patients in whom a deferred policy is inappropriate should not be entered into this study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Male

Total final enrolment

938

Key exclusion criteria

Not provided at time of registration.

Date of first enrolment

01/08/2000

Date of final enrolment

01/08/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)**Funder type**

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/1997	15/11/2019	Yes	No