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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

Registration date
19/08/2002

Overall study status
Completed

Last Edited
15/11/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

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. 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 measure
Not provided at time of registration.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/08/2000

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

Age group
Not Specified

Sex
Male

Target number of participants
Not provided at time of registration.

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
England

United Kingdom

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

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

Website
http://www.mrc.ac.uk

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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

Study outputs

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