

A phase III randomised trial comparing intermittent versus continuous androgen suppression for patients with prostate-specific-antigen (PSA) progression in the clinical absence of distant metastases following radiotherapy for prostate cancer

Submission date 31/05/2001	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 31/05/2001	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 18/10/2018	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

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Additional identifiers

Protocol serial number

NCIC PR7

Study information

Scientific Title

A phase III randomised trial comparing intermittent versus continuous androgen suppression for patients with prostate-specific-antigen (PSA) progression in the clinical absence of distant metastases following radiotherapy for prostate cancer

Acronym

Intercontinental Trial

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)

Not Specified

Health condition(s) or problem(s) studied

Prostate cancer

Interventions

1. Intermittent androgen suppression
2. Continuous androgen deprivation

Intervention Type

Other

Phase

Phase III

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2005

Eligibility**Key inclusion criteria**

1. Histologically or cytologically confirmed adenocarcinoma of the prostate prior to initiation of radiotherapy
2. Previous pelvic radiotherapy for prostate cancer
3. Serum PSA >3 ng/ml and higher than the lowest level recorded previously since the end of radiotherapy and must be done within 1 month prior to randomisation
4. Serum testosterone greater than or equal to 7 mmol/L and must be done within 1 month prior to randomisation
5. No definite evidence of metastatic disease
6. Chest X-ray performed within 8 weeks prior to randomisation and is negative for metastases
7. No radiotherapy in the 12 months preceding randomisation
8. No prior hormonal therapy (except neoadjuvant cytoreduction prior to radiotherapy or prostatectomy for a maximum duration of 8 months)
9. Eastern Cooperative Oncology Group (ECOG) performance status 0-1
10. Aged at least 16 years
11. Life expectancy >5 years
12. Able to complete QOL questionnaires
13. Within 28 days prior to randomisation: Bilirubin - NO greater than 1.5 x upper normal limit (UNL) aspartate aminotransferase (AST) (serum glutamic oxaloacetic transaminase [SGOT]) - NO greater than 1.5 x UNL alanine aminotransferase (ALT) (serum glutamic pyruvic transaminase [SGPT]) - NO greater than 1.5 x UNL lactic dehydrogenase (LDH) - NO greater than 1.5 x UNL Creatinine - NO greater than 1.5 x UNL
14. Adequate birth control for duration of study
15. Informed consent
16. Accessible for follow-up
17. Luteinising hormone-releasing hormone (LHRH) analogue and antiandrogen must begin within 5 working days of randomisation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Male

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2002

Date of final enrolment

31/12/2005

Locations

Countries of recruitment

United Kingdom

England

Canada

Study participating centre

Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)

Sutton, Surrey

United Kingdom

SM2 5NG

Sponsor information

Organisation

Individual Sponsor (UK)

Funder(s)

Funder type

Government

Funder Name

NCRN UK funding + external funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type
[Plain English results](#)

Details

Date created

Date added

Peer reviewed?
No

Patient-facing?
Yes