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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	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 31/05/2001	**Overall study status** Completed	
Last Edited 18/10/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Ms Sejal Patel

Contact details
Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)
Section of Epidemiology
Brookes Lawley Building
Cotswold Road
Sutton, Surrey
United Kingdom
SM2 5NG
+44 (0)20 8722 4062
Sejal.Patel@icr.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2002

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

Age group
Adult

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
01/01/2002

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Canada

England

United Kingdom

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)

Sponsor details
Prof David Dearnaley
The Royal Marsden NHS Trust

London
United Kingdom
SM2 5NG

Sponsor type
Research organisation

Website
http://www.ncic.cancer.ca

Funder(s)

Funder type
Government

Funder Name
NCRN UK funding + external funding

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?
Plain English results				No	Yes