

# 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

<b>Submission date</b> 31/05/2001	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/05/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 18/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**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**

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 cyto reduction 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?
<a href="#">Plain English results</a>				No	Yes