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

Submission date	Recruitment status	[X] Prospectively registered
31/05/2001	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
31/05/2001	Completed	Results
Last Edited	Condition category	[] Individual participant data
18/10/2018	Cancer	<ul><li>Record updated in last year</li></ul>

# 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

**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

#### 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 typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Plain English resultsNoYes