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A phase III study of neoadjuvant bicalutamide in patients with intermediate risk prostate cancer undergoing radiation therapy

Submission date 27/10/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/01/2005	**Overall study status** Completed	
Last Edited 18/02/2008	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
99-07

Study information

Scientific Title

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

Health condition(s) or problem(s) studied
Localised prostate cancer

Interventions
Bicalutamide 150 mg daily for 3 months before and 2 months during radiation therapy versus no hormonal therapy.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bicalutamide

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/1999

Completion date
30/06/2006

Eligibility

Key inclusion criteria
1. T1/T2a prostate cancer with:
1.1. Gleason 7, prostate specific antigen (PSA) less than 20 ng/ml
1.2. Gleason less than 7, PSA 10 - 20 ng/ml
2. T2b prostate cancer with:
2.1. PSA less than 20 ng/ml
2.2. Gleason less than or equal to 7

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
360

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/1999

Date of final enrolment
30/06/2006

Locations

Countries of recruitment
Canada

Study participating centre
610 University Avenue
Toronto

Canada
M5G 2M9

Sponsor information

Organisation
Princess Margaret Hospital (Canada) - Department of Radiation Oncology

Sponsor details
610 University Avenue
Toronto
Canada
M5G 2M9

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03zayce58

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Princess Margaret Hospital (Canada) - internal genitourinary (GU) group funds

Funder Name
AstraZeneca (Canada) - small unrestricted grant

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