

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/01/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 18/02/2008	Condition category 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

Dr Padraig Warde

Contact details

610 University Avenue

Toronto

Canada

M5G 2M9

+1 416 946 2122

padraig.warde@rmp.uhn.on.ca

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