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A randomised trial of a shorter radiation fraction schedule for the treatment of localised prostate cancer

Submission date
05/11/2007

Recruitment status
No longer recruiting

Registration date
05/11/2007

Overall study status
Completed

Last Edited
20/03/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ocog.ca/SMAP/Trials.aspx

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00304759

Secondary identifying numbers
MCT-78776

Study information

Scientific Title
A randomised trial of a shorter radiation fraction schedule for the treatment of localised prostate cancer

Acronym
PROFIT (PROstate Fractionated Irradiation Trial)

Study objectives
To determine whether a 4-week course of hypofractionated radiotherapy is as safe and effective as a standard 8-week course of radiotherapy for treatment of intermediate risk localised prostate cancer.

On 12/11/2008 this record was updated to include an amendment to the exclusion criteria and a change of sponsor. The initial sponsor was McMaster University (Canada) as this was where the Ontario Clinical Oncology Group (OCOG) was initially based, but this has now moved to the Henderson Research Centre. Please also note that at this time, Australia was added to the trial countries of recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Board of University Health Network, Toronto, Ontario, Canada, 16/01/2006, ref: 05-849-C
2. Research Ethics Board of McMaster University, Hamilton, Ontario, Canada, 21/02/2006, ref: 06-44

Approval for the amendment to the exclusion criteria was gained by the UHN on 16/05/2008 and the Hamilton Health Sciences on 19/08/2008.

Study design
Multicentre two-arm randomised parallel 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
Prostate cancer

Interventions
Conformal external beam radiotherapy.

Standard arm: 78 Gy in 39 fractions over 7.8 weeks (5 days a week)
Investigational arm: 60 Gy in 20 fractions over 4 weeks (5 days a week)

The below contact is for scientific and public queries.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Biochemical (PSA) relapse-free rate at 5 years post treatment.

Secondary outcome measures
1. Biochemical-Clinical Failure (BCF)
2. All-cause mortality
3. Prostate cancer specific mortality
4. Treatment-related toxicity
5. Health-related quality of life
6. Economic outcomes

Overall study start date
01/11/2005

Completion date
30/11/2012

Eligibility

Key inclusion criteria
1. Histologic diagnosis of carcinoma of the prostate without evidence of metastatic disease to the lymph nodes, bone or lung; within 6 months of recruitment
2. Intermediate risk prostate cancer, that is:
2.1. T1-2a, Gleason score 6, Prostate Specific Antigen [PSA] 10.1 - 20.0 ng/ml
2.2. T2b-c Gleason 6, PSA less than or equal to 20.0 ng/ml
2.3. T1-2, Gleason 7, PSA less than or equal to 20.0 ng/ml
3. Male prostate cancer patients 50 years old and above

Participant type(s)

Patient

Age group
Adult

Sex
Male

Target number of participants
1204

Key exclusion criteria
Current exclusion criteria as of 12/08/2014:
1. Previous therapy for carcinoma of the prostate other than biopsy or transurethral resection
2. Patients previously on more than 12 weeks of hormone therapy for treatment of their prostate cancer to be excluded from study
3. Any other active malignancy (untreated, progressive or recurrent), except for non-melanoma skin cancer. Any inactive malignancy diagnosed within 5 years of study entry, except for non-melanoma skin cancer.
4. Treatment plan cannot meet dose constraints for the hypofractionation arm of the trial
5. Previous pelvic radiotherapy
6. Inflammatory bowel disease

Previous exclusion criteria:
1. Previous therapy for carcinoma of the prostate other than biopsy or transurethral resection
2. Patients previously on more than 12 weeks of hormone therapy for treatment of their prostate cancer to be excluded from study
3. Prior or active malignancy other than non-melanoma skin cancer, or colon or thyroid cancer treated a minimum of five years prior to study entry and presumed cured
4. Treatment plan cannot meet dose constraints for the hypofractionation arm of the trial
5. Previous pelvic radiotherapy
6. Inflammatory bowel disease

Date of first enrolment
01/11/2005

Date of final enrolment
30/11/2012

Locations

Countries of recruitment
Australia

Canada

Study participating centre
Ontario Clinical Oncology Group (OCOG)
Hamilton, Ontario

Canada
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Sponsor information

Organisation
Ontario Clinical Oncology Group (OCOG) (Canada)

Sponsor details
Henderson Research Centre
711 Concession Street
Hamilton, Ontario
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L8V 1C3
+1 905 527 2299 ext 42626
a@b.com

Sponsor type
Research organisation

Website
http://www.ocog.ca

ROR
https://ror.org/003w29077

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) (ref: MCT-78776)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

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?
Results article	results	10/06/2017		Yes	No