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A randomised phase III multi-centre trial of Conventional or Hypofractionated High dose Intensity modulated radiotherapy for Prostate cancer

Submission date
09/09/2005

Recruitment status
No longer recruiting

Registration date
12/10/2005

Overall study status
Completed

Last Edited
04/06/2024

Condition category
Cancer

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

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-comparing-different-ways-of-giving-radiotherapy-for-prostate-cancer

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00392535

Secondary identifying numbers

CCR2482

Study information

Scientific Title
A randomised phase III multi-centre trial of Conventional or Hypofractionated High dose Intensity modulated radiotherapy for Prostate cancer

Acronym
CHHIP

Study objectives
To test the hypothesis that hypofractionated radiotherapy schedules for localised prostate cancer will improve the therapeutic ratio by either:
1. Improving tumour control
2. Reducing normal tissue side effects

Ethics approval required
Old ethics approval format

Ethics approval(s)
London MREC, 17/08/2004, ref: 04/MRE02/10

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
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
1. Control group: neoadjuvant hormone therapy and external beam radiotherapy (IMRT) 74 Gy in 37 fractions over 7.5 weeks.
2. Hypofractionation group one: neoadjuvant hormone therapy and external beam radiotherapy (IMRT) 57 Gy in 19 fractions over four weeks.

3. Hypofractionation group two: neoadjuvant hormone therapy and external beam radiotherapy (IMRT) 60 Gy in 20 fractions over four weeks.

Intervention Type
Mixed

Primary outcome measure
Acute and late radiation induced side-effects

Secondary outcome measures
1. Freedom from prostate cancer recurrence
2. Development of metastases
3. Recommencement of hormonal treatment for disease occurrence
4. Cause specific and overall survival
5. Aspects of quality of life and health economics
6. Models of normal tissue and tumour control

Overall study start date
18/10/2002

Completion date
17/06/2011

Eligibility

Key inclusion criteria
1. Histologically confirmed, previously untreated locally confined adenocarcinoma of the prostate
2. Clinical stage T1b T3a, N0, M0 (1997 TNM system)
3. Prostate Specific Antigen (PSA) less than 40 ng/ml
4. Estimated risk of lymph node metastases less than 30%
5. World Health Organisation (WHO) performance status zero or one
6. Normal blood count (Hb more than 11 g/dl, white blood cell count [WBC] more than 4000 /mm^3, platelets more than 100,000/mm^3)
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
3170 (Added 12/09/2011: 3216 actually recruited)

Total final enrolment
3216

Key exclusion criteria
1. Prior pelvic radiotherapy or radical prostatectomy
2. Previous androgen deprivation
3. Life expectancy less than ten years (less than five years for poorly differentiated cancers)
4. Previous active malignancy within the last five years other than basal cell carcinoma
5. Co-morbid conditions likely to impact on the advisability of radical radiotherapy (e.g. previously inflammatory bowel disease, previous colorectal surgery, significant bladder instability or urinary incontinence)
6. Full anticoagulation with e.g. Warfarin or Heparin
7. Hip prosthesis or fixation which would interfere with standard radiation beam configuration

Date of first enrolment
18/10/2002

Date of final enrolment
17/06/2011

Locations

Countries of recruitment
England

Ireland

New Zealand

Switzerland

United Kingdom

Study participating centre
Royal Marsden NHS Trust
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Institute of Cancer Research (UK)

Sponsor details

123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Research organisation

Website
http://www.icr.ac.uk

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Research organisation

Funder Name
CTAAC

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?
Plain English results				No	Yes
Other publications	prospective analysis study	01/01/2012		Yes	No
Results article	preliminary safety results	01/01/2012		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	01/08/2016		Yes	No

Protocol article	sub-study protocol	16/02/2018		Yes	No
Results article	sub-study results	01/01/2020	27/11/2019	Yes	No
Results article	sub-study results	01/12/2023	04/06/2024	Yes	No