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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	[_] Prospectively registered [X] Protocol
Registration date 12/10/2005	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 04/06/2024	**Condition category** Cancer	[_] 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

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00392535

Protocol serial number
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

Study type(s)
Treatment

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(s)
Acute and late radiation induced side-effects

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

Ireland

New Zealand

Switzerland

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

Sponsor information

Organisation
Institute of Cancer Research (UK)

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Research organisation

Funder Name
CTAAC

Results and Publications

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	preliminary safety results	01/01/2012		Yes	No
Results article	results	01/12/2015		Yes	No
Results article	results	01/08/2016		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
Protocol article	sub-study protocol	16/02/2018		Yes	No
Other publications	prospective analysis study	01/01/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes