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Radiotherapy and Androgen Deprivation In Combination After Local Surgery

Submission date	Recruitment status	[_] Prospectively registered
28/06/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
31/10/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/11/2026	Cancer	

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-trial-looking-at-radiotherapy-and-hormone-therapy-after-surgery-for-prostate-cancer

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00541047

Clinical Trials Information System (CTIS)
2006-000205-34

Protocol serial number

PR10

Study information

Scientific Title
Radiotherapy and Androgen Deprivation In Combination After Local Surgery

Acronym
RADICALS

Study objectives
RADICALS will test whether giving radiotherapy routinely, within a few months after surgery, rather than waiting for the Prostate-Specific Antigen (PSA) to rise, will reduce the proportion of men who die from prostate cancer. RADICALS will also test whether men receiving radiotherapy after surgery also benefit from the addition of androgen deprivation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Royal Free Hospital and Medical School Research Ethics Committee, 18/04/2007, ref: 07/Q0501 /48

Primary study design
Interventional

Study design
Randomized controlled trial with two separate randomisations

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Prostate cancer

Interventions
Current interventions as of 15/09/2014:
Radiotherapy timing randomisation:
Arm 1A: adjuvant radiotherapy (RT) to prostate bed
Arm 1B: observation policy with early salvage RT to prostate bed given in the event of biochemical failure

Hormone therapy duration randomisation:
Arm 2A: no hormone therapy with radiotherapy
Arm 2B: short-term hormone therapy (6 months) commencing approximately 2 months prior to radiotherapy
Arm 2C: long-term hormone therapy (24 months) commencing approximately 2 months prior to radiotherapy

Previous interventions:
Radiotherapy timing randomisation:
Arm 1A: adjuvant radiotherapy (RT) to prostate bed
Arm 1B: observation policy with early salvage RT to prostate bed given in the event of biochemical failure

Hormone therapy duration randomisation:
Arm 2A: no hormone therapy with radiotherapy
Arm 2B: short-term hormone therapy (4 months) commencing approximately 2 months prior to radiotherapy
Arm 2C: long-term hormone therapy (24 months) commencing approximately 2 months prior to radiotherapy

The previous sponsor for this trial (up to 15/09/2014) was:
Medical Research Council Clinical Trials Unit (UK)
Ian Viney
MRC Centre London
Stephenson House
158-160 North Gower Street
London
NW1 2DA
United Kingdom

Intervention Type
Other

Primary outcome(s)
Disease-specific survival (i.e., death due to prostate cancer)

Key secondary outcome(s)
1. Freedom from treatment failure
2. Clinical progression-free survival
3. Overall survival
4. Non-protocol androgen deprivation
5. Quality of life
6. Treatment toxicity

Completion date
28/07/2022

Eligibility

Key inclusion criteria
Patient has undergone radical prostatectomy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Male

Total final enrolment
4236

Key exclusion criteria
1. Androgen deprivation prior to radical prostatectomy
2. Bilateral orchidectomy
3. Prior pelvic radiotherapy
4. Other active malignancy likely to interefere with protocol treatment or follow-up
5. Known distant metastases from prostate cancer

Date of first enrolment
01/09/2006

Date of final enrolment
01/06/2015

Locations

Countries of recruitment
United Kingdom

England

Canada

Denmark

Ireland

Study participating centre
Academic Urology Unit
-
London
England
SM2 5PT

Sponsor information

Organisation

MRC Clinical Trials Unit at UCL

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK), ref: C7829/A6381

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Please see the unit Data Sharing Policy (https://www.ctu.mrc.ac.uk/our-research/other-research-policy/data-sharing/) and recent paper (https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-015-0604-6) regarding the rationale for a controlled access approach.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	RADICALS-RT	31/10/2020	08/12/2022	Yes	No
Results article	RADICALS-HD	16/05/2024	20/05/2024	Yes	No
Results article	RADICALS-HD	16/05/2024	20/05/2024	Yes	No
Protocol article	protocol	01/04/2007		Yes	No
Abstract results	RADICALS-HD	12/09/2022	08/12/2022	No	No
Other publications		28/09/2020	08/12/2022	Yes	No
Other publications	RADICALS-HD	06/07/2022	08/12/2022	Yes	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results	RADICALS-HD		06/11/2026	No	Yes
Plain English results	RADICALS-RT		06/11/2026	No	Yes
Statistical Analysis Plan	RADICALS-HD and RADICALS-RT	27/05/2022	08/12/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes