

Radiotherapy and Androgen Deprivation In Combination After Local Surgery

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| Submission date 28/06/2006 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 31/10/2006 | Overall study status Completed | <input checked="" type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 20/05/2024 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

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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Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-000205-34

ClinicalTrials.gov (NCT)

NCT00541047

Protocol serial number

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

Study design

Randomized controlled trial with two separate randomisations

Primary study design

Interventional

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

Phase

Phase III

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 interfere 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

United Kingdom

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 |

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|---|-------------------------------|------------|------------|-----|-----|
| 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 |
| 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 |