

# Radiotherapy and Androgen Deprivation In Combination After Local Surgery

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

## Study website

<http://www.radicals-trial.org/>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Rosalind Wright

### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2006-000205-34

### IRAS number

**ClinicalTrials.gov number**

NCT00541047

**Secondary identifying numbers**

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

**Study design**

Randomized controlled trial with two separate randomisations

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

Patient information can be found at: [http://www.radicals-trial.org/information\\_for\\_patients/patient\\_information\\_sheets.aspx](http://www.radicals-trial.org/information_for_patients/patient_information_sheets.aspx)

**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 measure**

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

## **Secondary outcome measures**

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

**Overall study start date**

01/09/2006

**Completion date**

28/07/2022

## Eligibility

**Key inclusion criteria**

Patient has undergone radical prostatectomy

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Male

**Target number of participants**

Approximately 4000 (to be confirmed, as this depends on actual recruitment)

**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**

Canada

Denmark

England

Ireland

United Kingdom

**Study participating centre**

**Academic Urology Unit**

London

United Kingdom

SM2 5PT

## **Sponsor information**

**Organisation**

MRC Clinical Trials Unit at UCL

**Sponsor details**

Institute of Clinical Trials & Methodology

90 High Holborn

2nd Floor

London

England

United Kingdom

WC1V 6LJ

+44 (0)20 7670 4651

mrcctu.radicals@ucl.ac.uk

**Sponsor type**

University/education

**Website**

<https://www.mrcctu.ucl.ac.uk/>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

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

**Alternative Name(s)**

CR\_UK, Cancer Research UK - London, CRUK

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Current publication and dissemination plan as of 22/05/2020:

RADICALS-RT comparison: biochemical progression-free survival (early/secondary outcome) – 2020

RADICALS-RT comparison: freedom from distant metastases (primary outcome) – mid 2022

RADICALS-HD comparison: metastases-free survival (new primary outcome) – mid 2022

Previous publication and dissemination plan:

RADICALS-RT comparison: biochemical progression-free survival (early/secondary outcome) – late 2019

RADICALS-RT comparison: freedom from distant metastases (primary outcome) – mid 2022

RADICALS-HD comparison: metastases-free survival (new primary outcome) – mid 2022

## Intention to publish date

30/09/2022

## 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?
<a href="#">Protocol article</a>	protocol	01/04/2007		Yes	No
<a href="#">Abstract results</a>	RADICALS-HD	12/09/2022	08/12/2022	No	No
<a href="#">Other publications</a>		28/09/2020	08/12/2022	Yes	No
<a href="#">Other publications</a>	RADICALS-HD	06/07/2022	08/12/2022	Yes	No
<a href="#">Results article</a>	RADICALS-RT	31/10/2020	08/12/2022	Yes	No
<a href="#">Statistical Analysis Plan</a>	RADICALS-HD and RADICALS-RT	27/05/2022	08/12/2022	No	No
<a href="#">Results article</a>	RADICALS-HD	16/05/2024	20/05/2024	Yes	No

[Results article](#)

RADICALS-HD

16/05/2024 20/05/2024 Yes

No