ISRCTN40814031 https://doi.org/10.1186/ISRCTN40814031

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
20/05/2024	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

Study website
http://www.radicals-trial.org/

Contact information

Type(s)
Scientific

Contact name
Dr Rosalind Wright

Contact details
Academic Urology Unit
Institute of Cancer Research and Royal Marsden Hospital
Downs Road
Sutton
London
United Kingdom
SM2 5PT
+44 (0)20 8661 3425
rosalind.wright@icr.ac.uk

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

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 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
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?
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
Results article	RADICALS-RT	31/10/2020	08/12/2022	Yes	No
Statistical Analysis Plan	RADICALS-HD and RADICALS-RT	27/05/2022	08/12/2022	No	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