

High dose therapy in localised cancer of the prostate using conformal radiotherapy techniques

Submission date 06/04/2000	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 06/04/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 25/10/2022	Condition category Cancer	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
RT01

Study information

Scientific Title
High dose therapy in localised cancer of the prostate using conformal radiotherapy techniques

Study objectives

To compare standard 64 Gy dose of conformal radiotherapy (CRT) with high dose 74 Gy CRT

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer

Interventions

1. Standard 64 Gy dose of conformal radiotherapy (CRT)
2. The other group receives high dose 74 Gy CRT

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Local tumour control, incidence of biochemical failure, metastases, survival, side effects of radiation, quality of life and health economic resources

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/12/2001

Eligibility**Key inclusion criteria**

1. Cancer of the prostate T1b-T3a, N0, M0
2. Prostate-Specific Antigen (PSA) less than 50 ng/ml
3. World Health Organisation (WHO) 0 or 1
4. No prior radiotherapy or prostatectomy

5. No previous androgen deprivation
6. No hip prosthesis or other condition precluding radiotherapy
7. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

Male

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

05/01/1998

Date of final enrolment

31/12/2001

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

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	results on erectile dysfunction and radiotherapy	01/09/2006		Yes	No
Results article	results on quality of life	01/02/2007		Yes	No
Results article	results on early toxicity of escalated Vs standard dose conformal radiotherapy	01/04/2007		Yes	No
Results article	results on escalated Vs standard dose conformal radiotherapy	01/06/2007		Yes	No
Results article	results on correlations between spatial distribution of the dose to the rectal wall and late rectal toxicity	07/11/2009		Yes	No
Results article	results on dose-volume constraints to reduce rectal side effects	01/03/2010		Yes	No
Results article	results	01/04/2010		Yes	No
Results	modellin late rectal toxicities results	07/04			

article		/2011	Yes	No
Results	results	01/11		
article		/2011	Yes	No
Results	additional rectal toxicity endpoint results	01/03		
article		/2012	Yes	No
Results	results	01/06		
article		/2012	Yes	No
Results	long-term results	01/04		
article		/2014	Yes	No
Results	two-years postradiotherapy biopsies results	01/06	15/03	
article		/2018	/2019	Yes
Protocol	protocol	01/08		No
article		/2004	Yes	
Protocol	protocol	01/07		No
article		/2006	Yes	
Other	questionnaire	01/11		No
publications		/2004	Yes	
Other	prospective analysis study	01/01		No
publications		/2012	Yes	
Other	secondary data analysis	01/08		No
publications		/2017	Yes	
Plain				
English			No	Yes
results				