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Dose escalation to intraprostatic tumour nodules in localised prostate cancer

Submission date 17/08/2011	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 17/08/2011	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 29/09/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-at-increasing-dose-of-radiotherapy-to-areas-of-cancer-inside-prostate-gland-delineate

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
10309

Study information

Scientific Title
Dose EscaLation to Intraprostatic tumour Nodules in localisEd prostATE cancer: A phase II study examining the toxicity and feasibility of a dose escalated boost to a magnetic resonance imaging identified tumour nodule or nodules in localised prostate cancer

Acronym
DELINEATE

Study objectives
Dose Escalation to Intra-prostatic Tumour Nodules in Localised Prostate Cancer
To assess the toxicity and feasibility of a dose escalated intensity-modulated radiotherapy boost to tumour nodules within the prostate using anatomical and functional magnetic resonance (MR) imaging to identify tumour. The aim is to maintain current levels of late toxicity.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/LO/0510

Primary study design
Interventional

Study design
Non-randomised; Interventional; Design type: Process of Care, Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: National Cancer Research Network; Subtopic: Prostate Cancer; Disease: Prostate

Interventions
Interventions as of 03/05/2017:
350 patients to be recruited and have MRI scans to diagnose intra-prostatic tumour nodules. Intra-prostatic tumour lesions will be treated with a radiotherapy boost.

Radiotherapy boost: A dose escalated external beam radiotherapy boost to intraprostatic tumour nodules within the prostate gland; Follow Up Length: 60 month(s); Study Entry : Registration only

Original interventions:
100 patients to be recruited and have MRI scans to diagnose intra-prostatic tumour nodules. 50% of patients expected to have lesions and so 50 patients to be treated with a radiotherapy boost

Radiotherapy boost: A dose escalated external beam radiotherapy boost to intraprostatic tumour nodules within the prostate gland; Follow Up Length: 60 month(s); Study Entry : Registration only

Intervention Type
Other

Phase
Phase II

Primary outcome(s)
Late rectal toxicity; Timepoint(s): 12 months

Key secondary outcome(s)
1. Acute genitourinary (Gu) and gastrointestinal (GI) toxicity; Timepoint(s): 18 weeks
2. Biochemical Recurrence; Timepoint(s): 24 months
3. Late GU and GI toxicity; Timepoint(s): 12 months and 24 months
4. Quality of Life Scores; Timepoint(s): 24 months

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Age more than or equal to 18 years
2. Histologically confirmed adenocarcinoma of the prostate
3. National Collaborative Cancer Network+ (NCCN) risk groups intermediate or high risk localised prostate cancer
4. Normal blood count [haemoglobin (Hb) > 11g/dl, white blood cell (WBC) > 4000/mm^3, platelets > 100,000/mm^3]
5. World Health Organisation (WHO) performance status 0 or 1
6. Life expectancy of 10 years or more
7. Written informed consent
8. Patients must be prepared to attend follow-up
9. For template biopsy sub-study must be considered fit for general / spinal anaesthetic; Target Gender: Male ; Lower Age Limit 18 no age limit or unit specified

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Male

Total final enrolment
265

Key exclusion criteria
1. Prior radiotherapy to the prostate or pelvis
2. Bilateral hip replacement
3. Prior hormone therapy

4. Radical prostatectomy
5. Lymph Node Risk > 30%
6. National Collaborative Cancer Network+ (NCCN) Favourable Risk Group
7. Evidence of seminal vesicle invasion, nodal or metastatic disease
8. Any previous invasive cancer in the past 5 years, with the exception of non-melanoma skin cancer
9. Patients with medical contraindication to magnetic resonance imaging (MRI) scanning

Date of first enrolment
13/07/2011

Date of final enrolment
30/10/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Downs Road
Sutton
United Kingdom
SM2 5PT

Sponsor information

Organisation
Institute for Cancer Research (UK)

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (CRUK) (UK)

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
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/09/2022	29/09/2022	Yes	No