

Dose escalation to intraprostatic tumour nodules in localised prostate cancer

Submission date 17/08/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/08/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/09/2022	Condition category Cancer	<input type="checkbox"/> 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

Contact name

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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

Study design

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

Primary study design

Interventional

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/mm³, platelets > 100,000/mm³]
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