# Dose escalation to intraprostatic tumour nodules in localised prostate cancer

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

#### 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

Ms Annie Gao

#### Contact details

Downs Road Sutton United Kingdom SM2 5PT

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annie.gao@rmh.nhs.uk

# 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) >  $4000/mm^3$ , 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes