

# A trial of prostate radiotherapy in conjunction with carbogen and nicotinamide

<b>Submission date</b> 06/02/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/02/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/09/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-radiotherapy-with-carbogen-and-nicotinamide-prostate-cancer-procon>

## Contact information

### Type(s)

Scientific

### Contact name

Dr Kent Yip

### Contact details

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## Additional identifiers

### EudraCT/CTIS number

2010-021886-63

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers

## Study information

### Scientific Title

A trial of PROstate radiotherapy in CONjunction with carbogen and nicotinamide (PROCON)

### Acronym

PROCON

### Study objectives

To investigate the use of carbogen and nicotinamide during a course radiotherapy for locally advanced prostate cancer to overcome tumour hypoxia.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

ref: 11/SC/0064

### Study design

Non-randomised interventional trial

### Primary study design

Interventional

### Secondary study design

Non randomised study

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Prostate cancer

### Interventions

The use of carbogen and nicotinamide during radiotherapy.

### Intervention Type

Drug

### Phase

Phase II

**Drug/device/biological/vaccine name(s)**

Carbogen, nicotinamide

**Primary outcome measure**

PSA progression-free survival measured at 5 years

**Secondary outcome measures**

Short-term and long-term GU and GI toxicity following treatment

**Overall study start date**

16/12/2011

**Completion date**

01/09/2013

## **Eligibility**

**Key inclusion criteria**

1. Histological diagnosis of prostate adenocarcinoma of Gleason grade 3+3 or higher
2. Radical radiotherapy is considered to be appropriate treatment
3. Any of: PSA > 20ng/ml, Gleason grade > 8, T3 disease on MRI
4. Patients must have radiographically documented measurable disease on pelvic MRI scan within 3 months of trial entry
5. Age over 18 with no upper age limit
6. Before patient registration, written informed consent must be given according to GCP and local regulations.
7. Male participants
8. Lower Age Limit 18 years

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Male

**Target number of participants**

Planned Sample Size: 50; UK Sample Size: 50

**Total final enrolment**

50

**Key exclusion criteria**

1. Metastatic disease (including pelvic lymph node metastases) on conventional imaging including pelvic MRI scan and isotope bone scan within 3 months of trial entry
2. PSA>50
3. T4 disease on pelvic MRI scan within 3 months of trial entry
4. Prior treatment for prostate cancer, either local or systemic (other than neoadjuvant androgen deprivation for a period of less than 3 months)
5. Current active malignancy other than prostate cancer or nonmelanomatous skin cancer
6. Previous radiotherapy to the pelvis
7. Comorbid conditions such that the technique of external beam radiotherapy is inappropriate
8. Contraindication to MRI (only applicable to patients that are being considered for entry into the imaging component of the study)
9. Current treatment with an ACE inhibitor
10. Any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and followup schedule; those conditions should be discussed with the patient before registration in the trial

**Date of first enrolment**

16/12/2011

**Date of final enrolment**

01/09/2013

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Mount Vernon Hospital**

Northwood

United Kingdom

HA6 2RN

## **Sponsor information**

**Organisation**

East and North Hertfordshire Hospitals NHS Trust (UK)

**Sponsor details**

Lister Hospital

Coreys Mill Lane

Stevenage

England

United Kingdom  
SG1 4AB  
+44 (0)1438 314333  
abc@email.com

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.enherts-tr.nhs.uk/our-hospitals/lister/>

**ROR**

<https://ror.org/02ryc4y44>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Prostate Cancer Charity (UK)

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****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?
<a href="#">Plain English results</a>			15/09/2022	No	Yes
<a href="#">HRA research summary</a>			28/06/2023	No	No