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A trial of prostate radiotherapy in conjunction with carbogen and nicotinamide

Submission date 06/02/2012	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 06/02/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/09/2022	**Condition category** Cancer	[_] Individual participant data [_] 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

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Additional identifiers

EudraCT/CTIS number
2010-021886-63

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

9930

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?
Plain English results			15/09/2022	No	Yes
HRA research summary			28/06/2023	No	No