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A multicentre randomised trial of radical radiotherapy with carbogen in the radical radiotherapy of locally advanced bladder cancer

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 01/07/2001	**Overall study status** Completed	
Last Edited 28/10/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00033436

Secondary identifying numbers
BCON

Study information

Scientific Title
A multicentre randomised trial of radical radiotherapy with carbogen in the radical radiotherapy of locally advanced bladder cancer

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Bladder (advanced)

Interventions
All patients receive Radiotherapy: Either 55 Gy in 20 daily fractions Or 64 Gy in 32 daily fractions. Treatments will be given daily five times per week treating all fields daily.

Patients are then randomised to:
1. Control (no further treatment)
2. Carbogen 2% CO2 (Carbogen will be delivered through a closed breathing system at a flow rate of 15 L/min of carbogen, to commence 5 min before delivery of radiation, and to commence throughout treatment) plus Nicotinamide: 60 mg/kg taken orally 1.5-2 hours before radiation.

Intervention Type
Drug

Phase

Phase III

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

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2000

Completion date
31/12/2006

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Histologically proven transitional cell carcinoma of the bladder
3. Muscle invasive carcinoma (Stage T2 or T3) of any grade; G3 superficial bladder cancer (T1) or prostatic invasion T4a
4. Ability to give informed consent
5. Capable of complying with the use of a closed breathing system delivering carbogen through either a mask or a mouthpiece with nasal clip
6. No squamous or adenocarcinoma of the bladder
7. No locally advanced T4b carcinoma
8. No presence of distant metastasis or enlarged lymph nodes on Computed Tomography (CT) staging scan of the pelvis
9. No co-existing respiratory disease that contra-indicates delivery of 95% oxygen
10. No impaired renal or hepatic function
11. No ischeamic heart disease or peripheral vascular disease requiring treatment with diuretics or ACE inhibitors

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/10/2000

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Cancer Research UK (CRUK) (UK)

Sponsor details
PO Box 123
Lincoln's Inn Fields
London
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Sponsor type
Charity

Website
http://www.cancer.org.uk

ROR
https://ror.org/054225q67

Funder(s)

Funder type
Charity

Funder Name
Cancer Reseach 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?
Results article	early results	01/04/2009		Yes	No
Results article	10-year results	06/03/2021	11/03/2021	Yes	No
Plain English results			28/10/2021	No	Yes