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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

UKCCCR Register Co-ordinator MRC Clinical Trials Unit 222 Euston Road London United Kingdom NW1 2DA

Additional identifiers

ClinicalTrials.gov (NCT) NCT00033436

Protocol serial number 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

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

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

Sponsor information

Organisation

Cancer Research UK (CRUK) (UK)

ROR

https://ror.org/054225q67

Funder(s)

Funder type

Charity

Funder Name

Cancer Reseach UK

Results and Publications

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