

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

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| Submission date 01/07/2001 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 01/07/2001 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 28/10/2021 | Condition category Cancer | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr - -

Contact details

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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 ischemic 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

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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 Research 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 |