ISRCTN68324339 https://doi.org/10.1186/ISRCTN68324339

2x2 factorial randomised phase III study comparing standard versus whole bladder volume radiotherapy with and without synchronous chemotherapy in muscle invasive bladder cancer

Submission date 01/07/2001	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 01/07/2001	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 18/05/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00024349

Protocol serial number
BC2001

Study information

Scientific Title
2x2 factorial randomised phase III study comparing standard versus whole bladder volume radiotherapy with and without synchronous chemotherapy in muscle invasive bladder cancer

Study objectives
Added 31/05/2011:
Study hypothesis: BC2001 is a multi-centred randomised controlled trial which aims:
1. To investigate the efficacy and toxicity of synchronous chemo-radiotherapy in conservative management of invasive bladder cancer compared to radiotherapy alone.
2. To investigate whether modifying the volume of bladder irradiated by the full dose of radiotherapy can reduce toxicity of radiotherapy in the conservative treatment of invasive bladder cancer, without impacting on local control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West 5 Research Ethics Committee, 05/03/2001, ref: MREC 00/8/075

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Four possible randomisations as follows:
1. Synchronous 5-Fluorouracil (5-FU) and Mitomycin with standard radiotherapy (to the whole bladder)
2. Synchronous 5-FU and Mitomycin with whole bladder volume radiotherapy
3. Standard radiotherapy to the whole bladder and no chemotherapy
4. Whole bladder volume radiotherapy and no chemotherapy

Intervention Type
Mixed

Primary outcome(s)

Added 02/06/2011:
Loco-regional (Ui.e. pelvic nodes & bladderU) disease free survival. The particular time point of interest is 2 years post randomisation

Key secondary outcome(s))
Secondary endpoint:
Disease free survival, Metastases free survival, Late toxicity at 1 and 2 years as assessed by RTOG and Lent Som toxicity scores, bladder capacity and Fact-BL QoL score. This endpoint is of particular importance in the radiotherapy comparison.

Tertiary endpoints:
1. Acute toxicity
2. Cystoscopic local control at 6 months, 1 year and 2 years post randomisation
3. Rate of salvage cystectomy
4. Overall survival

Completion date
31/08/2011

Eligibility

Key inclusion criteria
1. Aged 18 or over
2. Histologically proven invasive bladder carcinoma (adenocarcinoma, transitional or squamous cell carcinoma)
3. Localised muscle invasive carcinoma either surgically or by imaging (T2-T4a, N0, M0)
4. Patients with multiple tumours at the time of randomisation are not eligible for the radiotherapy volume randomisation but may be randomised to whole bladder radiotherapy with or without chemotherapy
5. World Health Organisation (WHO) performance status 0-2 Leucocytes >4.0 x 10(9)/ l; Platelets >100 x 10(9)/l Glomerular filtration rate (GFR) >25 ml/min Serum bilirubin <1.5 upper limit of reference range (ULRR) alanine amino transferase (ALT) or aspartate amino transferase (AST) <1. 5 x ULRR
6. Patient available for long term follow up and in the opinion of the investigator, able to receive radical radiotherapy
7. Patients written informed consent
8. Able to understand and complete the QoL questionnaire (patient can enter study without QoL but ALL are invited)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
458

Key exclusion criteria
1. Uncontrolled systemic disease which would preclude the patient from the study
2. Pregnancy
3. Other malignancy within the previous 2 years (other than adequately treated BCC of the skin or adequately treated in situ carcinoma of the cervix uteri)
4. Previous malignancy that is likely to interfere with protocol treatment
5. Inflammatory bowel disease
6. Previous pelvic radiotherapy
7. Bilateral hip replacements compromising accurate radiotherapy planning

Date of first enrolment
03/08/2001

Date of final enrolment
31/08/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU)
Sutton
United Kingdom
SM2 5NG

Sponsor information

Organisation
Individual Sponsor (UK)

Funder(s)

Funder type

Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	19/04/2012		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	01/01/2015		Yes	No
Results article		13/05/2022	18/05/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Plain English results				No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes