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A Trial of Accelerated Fractionation in Localised Invasive Bladder Cancer

Submission date 19/08/2002	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2002	**Overall study status** Completed	
Last Edited 04/01/2012	**Condition category** 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ICR/CUCG

Study information

Scientific Title

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)
Hospital

Study type(s)
Not Specified

Participant information sheet

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

Interventions
1. Schedule A: Radiotherapy, an accelerated fractionation schedule of 60.8 Gy given in thirty-two fractions over 26 days. Radiotherapy is given twice daily (morning dose of 1.8 Gy and 2.0 Gy in the afternoon) as 22.8 Gy in twelve fractions over 8 days, followed by a 3 to 6 day gap, followed by 38 Gy in twenty fractions over 2 weeks.
2. Schedule B: Radiotherapy, a conventional fractionation schedule of 64 Gy given in thirty-two fractions over 6.5 weeks. Radiotherapy is given once per day 5 days per week.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/01/1988

Completion date
31/12/1998

Eligibility

Key inclusion criteria
1. Stage T2 or T3 NXMO carcinoma of the bladder defined either by clinical findings or by histopathology
2. If nodes are assessed N1 patients (single node <2 cm) are eligible, N2 and N3 patients are excluded
3. Patients with severe concurrent general medical illness especially those with inflammatory bowel disease, other malignancies (except skin cancer), recent myocardial infarction (within 3 months) or previous major pelvic surgery are excluded

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/1988

Date of final enrolment
31/12/1998

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
The Institute of Cancer Research (UK)

Sponsor details
123 Old Brompton Road
London
United Kingdom
SW7 3RP

Sponsor type
Government

Website
http://www.icr.ac.uk

ROR
https://ror.org/043jzw605

Funder(s)

Funder type
Research organisation

Funder Name
Institute of Cancer Research (UK)

Alternative Name(s)
Institute of Cancer Research - CIHR, CIHR Institute of Cancer Research, L'Institut du cancer, Institut du cancer, ICR - CIHR, ICR, IC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Canada

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	01/04/2005		Yes	No