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A randomised trial of radical radiotherapy in pT1g3 NXM0 bladder cancer

Submission date 06/04/2000	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/04/2000	**Overall study status** Completed	
Last Edited 29/10/2021	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00002490

Secondary identifying numbers
BS06

Study information

Scientific Title
A randomised trial of radical radiotherapy in pT1g3 NXM0 bladder cancer

Study objectives
1. To determine the efficacy of radical radiotherapy in reducing the incidence of progression of pT1G3 transitional cell carcinoma of the bladder to muscleinvasive disease and subsequent disease fatality.
2. To assess the toxicity of the radiotherapy.
3. To determine the incidence of carcinoma in situ elsewhere in the bladder and the influence of this on the subsequent clinical outcome.

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)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Cancer

Interventions
1. One group receives radical radiotherapy
2. The other group receives intravesical treatment with no radiotherapy

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
01/09/1991

Completion date
30/04/2003

Eligibility

Key inclusion criteria
1. A new diagnosis of pT1G3 NXMO tumour or tumours made within 6 months of randomisation. (A prior history of bladder tumours of a lower stage or grade is admissible)
2. No history of urothelial tumours of a higher stage
3. Muscle from the base of tumour is histologically clear
4. Widespread Carcinoma In Situ (CIS) causing severe symptoms is not admissible
5. No clinical, radiological or biochemical evidence of distant metastases
6. No prior therapy with intravesical chemotherapy or BCG other than a single adjuvant treatment
7. No concomitant or previous malignancy other than non-melanomatous skin cancer or cervical intraepithelial neoplasia (CIN)
8. WHO performance status of 0-2
9. Complete resection of all tumours
10. Deemed suitable to undergo radiotherapy and cystoscopy follow-up

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
200

Total final enrolment
210

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/09/1991

Date of final enrolment

30/04/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Sponsor details
20 Park Crescent
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W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

Sponsor type
Research council

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

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council (MRC) (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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?
Abstract results		01/06/2005		No	No
Results article	results	01/09/2007		Yes	No
Plain English results		08/09/2009	29/10/2021	No	Yes