

A randomised trial of radical radiotherapy in pT1g3 NXM0 bladder cancer

Submission date 06/04/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/04/2000	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 29/10/2021	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 Danielle Andrews

Contact details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA
-
none@provided.com

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00002490

Protocol serial number
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 muscle-invasive 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit
London
United Kingdom
NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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				

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