A randomised trial of radical radiotherapy in pT1g3 NXM0 bladder cancer

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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none@provided.com

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

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 London United Kingdom 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