ISRCTN82694463 https://doi.org/10.1186/ISRCTN82694463

A phase III study of primary chemotherapy in T2 (G3), T3 and T4a; N0 or NX; M0 transitional cell carcinoma (TCC) of the bladder

Submission date 13/03/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/03/2001	**Overall study status** Completed	
Last Edited 09/07/2014	**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

Protocol serial number
BA06

Study information

Scientific Title

Study objectives

1. To determine the survival advantage of the addition of three cycles of cisplatin, methotrexate and vinblastine (CMV) chemotherapy prior to definitive radiotherapy and/or cystectomy
2. To determine the morbidity and mortality of definitive treatment together with any additional toxicity arising from CMV chemotherapy
3. To determine the prognostic significance of downstaging to T0 following CMV chemotherapy

Collaboration with the European Organization for Research and Treatment of Cancer (EORTC), Australian Bladder Cancer Study Group, Norwegian Bladder Cancer Study Group, Club Urologico Espanol de Tratamiento Group, Finnbladder and National Cancer Institute, Canada.

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

Study type(s)
Treatment

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

Interventions
Primary chemotherapy in T2 (G3), T3 and T4a; N0 or NX; M0 TCC of the bladder

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Chemotherapy

Primary outcome(s)
Survival

Key secondary outcome(s)
Not provided at time of registration

Completion date
10/07/1995

Eligibility

Key inclusion criteria
1. Histologically proven TCC of the bladder with biopsy-proven muscle invasion
2. Tumours considered curable (less than or equal to 7 cm)
3. GFK ≥50 ml/min (Cockcroft)
4. White blood count (WBC) >3.5 x 10^9/L and platelet count >100 x 10^9/L

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/12/1989

Date of final enrolment
10/07/1995

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

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	14/08/1999		Yes	No