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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

Contact name
Dr Barbara Uscinska

Contact details
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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Survival

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/12/1989

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

Age group
Not Specified

Sex
Both

Target number of participants
915 required, 975 entered

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
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

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