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

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) $>3.5 \times 10^9/L$ and platelet count $>100 \times 10^9/L$

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, 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
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes