

A Multicentre Randomised Feasibility Study of Adjuvant Chemotherapy (CT) following Radical Primary Treatment for Transitional Cell Carcinoma (TCC) of the Bladder

Submission date 19/08/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/08/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/05/2012	Condition category Cancer	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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 - -

Contact details

UKCCCR Register Co-ordinator
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

Additional identifiers

Protocol serial number

EMI Study

Study information

Scientific Title

Study objectives

Not provided at time of registration

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

Cancer of bladder (advanced)

Interventions

Total Cystectomy or Radical RT +/- CT

CT: Methotrexate 30 mg/m² (days 1, 15, 22) Vinblastine 3 mg/m² (days 2, 15, 22) Adriamycin 30 mg/m² (day 2) Cisplatin 70 mg/m² (day 2) every 28 days, maximum of three cycles

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Methotrexate, vinblastine, adriamycin

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

15/02/2002

Eligibility**Key inclusion criteria**

1. Histologically confirmed invasive TCC of the bladder
2. Stage T2, T3a, T3b, T4a, N0 or T(any), N1/N2
3. Patient has undergone a complete resection at cystectomy or has received radical radiotherapy with curative intent
4. Fit enough to undergo combination chemotherapy
5. Creatinine clearance >60ml/min within 10 weeks of primary treatment
6. Haematological counts within 4 weeks before randomisation: White Blood Count (WBC) >3x10⁹/l Platelets >100 x10⁹/l Haemoglobin >10g/dl
7. Patient must be able to commence CT within 12 weeks of completion of primary treatment
8. Written informed consent

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/01/2000

Date of final enrolment

15/02/2002

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

UKCCCR Register Co-ordinator

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Northern Research and Development (UK)

Funder(s)

Funder type

Research organisation

Funder Name

Northern Research and Development (UK)

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				Yes	No