ISRCTN16638426 https://doi.org/10.1186/ISRCTN16638426

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

Registration date
19/08/2002

Overall study status
Completed

Last Edited
30/05/2012

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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/m^2 (days 1, 15, 22) Vinblastine 3 mg/m^2 (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) >3x10^9/l Platelets >100 x10^9/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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes