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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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 measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
UKCCCR Register Co-ordinator
London
United Kingdom
NW1 2DA

Sponsor information

Organisation
Northern Research and Development (UK)

Sponsor details
-
Durham
United Kingdom
-

Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
Northern Research and Development (UK)

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				Yes	No