ISRCTN11318989 https://doi.org/10.1186/ISRCTN11318989

A randomised trial to compare the effects of methotrexate and vinblastine with cisplatin, methotrexate and vinblastine in the treatment of T4b, locally recurrent and metastatic transitional cell carcinoma

Submission date	Recruitment status	[_] Prospectively registered
19/08/2002	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/08/2002	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/10/2019	Cancer	

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
BA07

Study information

Scientific Title
A randomised trial to compare the effects of methotrexate and vinblastine with cisplatin, methotrexate and vinblastine in the treatment of T4b, locally recurrent and metastatic transitional cell carcinoma

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
Bladder (advanced)

Interventions
Patients are randomised to one of two treatment arms:
1. Arm A: Chemotherapy with methotrexate and vinblastine to be repeated every 21 days for a maximum of six cycles.
2. Arm B: Chemotherapy with cisplatin, methotrexate and vinblastine to be repeated every 21 days for a maximum of six cycles.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Methotrexate and Vinblastine with Cisplatin

Primary outcome(s)
Not provided at time of registration.

Key secondary outcome(s))
Not provided at time of registration.

Completion date
31/07/1995

Eligibility

Key inclusion criteria
1. Transitional cell carcinoma (which may contain elements of squamous or adenocarcinoma) arising from a primary at any site in the urinary tract, and in one of the following groups: Initial presentation with stage T4b disease only: Localised invasive pelvic relapse after definitive radiotherapy (when cystectomy not possible or refused): Metastatic disease at any site (patients with completely resected metastases, including those with pelvic nodes, are eligible)
2. Glomerular filtration rate of more than 50 ml/min. Patients with impaired urinary function secondary to ureteric obstruction may have this relieved with stents or ureterostomy. If renal function then recovers the patients will be eligible
3. Adequate haematological function
4. No previous systemic chemotherapy
5. No concomitant or previous malignancy other than basal cell carcinoma of the skin or carcinoma in situ of the cervix
6. No medical contraindications to treatment protocols

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
01/07/1990

Date of final enrolment
31/07/1995

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
UKCCCR Register Co-ordinator
London

United Kingdom
NW1 2DA

Sponsor information

Organisation
Medical Research Council (MRC) (UK)

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory 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	01/10/1998	24/10/2019	Yes	No