

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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.

Primary study design

Interventional

Study design

Randomised controlled trial

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