

# 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

<b>Submission date</b> 19/08/2002	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2002	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/10/2019	<b>Condition category</b> Cancer	<input type="checkbox"/> 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

**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, 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?
<a href="#">Results article</a>	results	01/10/1998	24/10/2019	Yes	No