

# A multicentre, prospective, randomised study of the value of a single dose of intravesical Mitomycin-C in preventing the development of bladder tumours following nephroureterectomy for transitional cell carcinoma (TCC) of the upper urinary tract

<b>Submission date</b> 29/07/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 02/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 17/10/2018	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/a-trial-looking-at-giving-chemotherapy-into-the-bladder-after-surgery-for-kidney-cancer>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

**Protocol serial number**

0062/WASH/2000

**Study information****Scientific Title**

A multicentre, prospective, randomised study of the value of a single dose of intravesical Mitomycin-C in preventing the development of bladder tumours following nephroureterectomy for transitional cell carcinoma (TCC) of the upper urinary tract

**Acronym**

ODMIT-C

**Study objectives**

The hypothesis is that a single dose of intravesical Mitomycin-C prevents tumour recurrence in the bladder following nephroureterectomy for a transitional cell carcinoma of the upper urinary tract.

**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)**

Prevention

**Health condition(s) or problem(s) studied**

Upper tract TCC bladder

**Interventions**

Intravesical instillation of Mitomycin-C post operatively versus no Mitomycin-C

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Mitomycin-C

**Primary outcome(s)**

Incidence of tumour recurrence at 1 year post nephroureterectomy

### **Key secondary outcome(s)**

To study the post surgical survival of these patients over five years.

### **Completion date**

01/12/2007

## **Eligibility**

### **Key inclusion criteria**

1. A new clinical diagnosis of a transitional cell tumour of the upper urinary tract above the intramural ureter
2. A negative cystoscopy for TCC bladder within one month of the nephroureterectomy
3. A nephroureterectomy that is planned to be performed in such a way that there is early distal ligation of the ureter prior to the mobilisation of the tumour. The intramural portion of the ureter may be resected prior to the open part of the operation, taken at the open operation with a cuff of bladder or everted at the end of the operation and resected endoscopically according to surgical preference.
4. Have a life expectancy of at least one year
5. Informed consent to participate (written and witnessed)

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. The histology of the upper tract tumour does not confirm a transitional cell carcinoma
2. Stage N1 or M1
3. Had additional systemic chemotherapy or additional intravesical Mitomycin-C at follow up cystoscopies
4. Existing or previous transitional cell carcinoma of bladder
5. Children, pregnant women excluded
6. Life expectancy less than one year
7. Known sensitivity to Mitomycin-C

### **Date of first enrolment**

20/07/2000

### **Date of final enrolment**

01/12/2007

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

**Guy's Hospital**

London

United Kingdom

SE1 9RT

# Sponsor information

## Organisation

Sussex NHS Research Consortium (UK)

# Funder(s)

## Funder type

Charity

## Funder Name

Guy's and St. Thomas' Charity (UK)

## Alternative Name(s)

Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## 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	01/10/2011		Yes	No
<a href="#">Plain English results</a>				No	Yes