

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

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

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 measure

Incidence of tumour recurrence at 1 year post nephroureterectomy

Secondary outcome measures

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

Overall study start date

20/07/2000

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

Age group

Adult

Sex

Both

Target number of participants

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**

England

United Kingdom

Study participating centre

Guy's Hospital

London

United Kingdom

SE1 9RT

Sponsor information**Organisation**

Sussex NHS Research Consortium (UK)

Sponsor details

Research Department

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Sponsor type

Government

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

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?
Plain English results				No	Yes
Results article	results	01/10/2011		Yes	No