ISRCTN36343644 https://doi.org/10.1186/ISRCTN36343644

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

Registration date
02/09/2005

Overall study status
Completed

Last Edited
17/10/2018

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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