

A randomised trial of intravesical irrigation in superficial bladder cancer followed by treatment with epodyl or mitomycin C at the time of first recurrence

Submission date 13/03/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 13/03/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 19/02/2018	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BS04

Study information

Scientific Title

A randomised trial of intravesical irrigation in superficial bladder cancer followed by treatment with epodyl or mitomycin C at the time of first recurrence

Study objectives

1. To detect the reduction, if any, of recurrence following irrigation of the bladder with glycine following complete resection of newly diagnosed bladder cancer
2. To compare the effect of Mitomycin-C against Epodyl in patients who develop recurrent superficial tumour following the initial transurethral resection in preventing further recurrence

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)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Bladder cancer

Interventions

Epodyl or mitomycin C

Follow-up: 3 monthly for 1st year, 6 monthly for 2nd year, annually thereafter.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Epodyl or mitomycin C

Primary outcome measure

Recurrence free survival

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/1987

Completion date

01/12/1995

Eligibility**Key inclusion criteria**

1. Newly diagnosed superficial bladder cancer suitable for complete endoscopic resection
2. Transitional cell carcinoma limited to the bladder, no evidence of carcinoma in the upper tracts
3. World Health Organisation (WHO) performance status 0-2
4. Expected survival at least 3 years
5. White count greater than $3 \times 10^9/L$ and platelets greater than $100 \times 10^9/L$
6. No untreated urinary tract infection

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

1000

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/07/1987

Date of final enrolment

01/12/1995

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

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Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council (MRC) (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

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