

A randomised trial of epirubicin versus mitomycin C at the time of first recurrence in superficial bladder cancer

Submission date 28/02/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/02/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 13/02/2018	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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

BS07

Study information

Scientific Title

A randomised trial of epirubicin versus mitomycin C at the time of first recurrence in superficial bladder cancer

Study objectives

1. To detect the reduction, if any, in recurrence following irrigation of the bladder with glycine or saline for a minimum of 18 hours after complete resection of newly-diagnosed superficial bladder cancer.
2. To compare the effect of Mitomycin C against Epodyl in preventing further recurrence in patients who have developed a recurrent superficial tumour after the initial transurethral resection.

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 below to request a patient information sheet

Health condition(s) or problem(s) studied

Bladder cancer

Interventions

First randomisation is between irrigation of the bladder with glycine/saline and no irrigation. The second randomisation is between Epodye and mitomycin C.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Epirubicin versus mitomycin C

Primary outcome measure

Local recurrence, time to progression, metastases, morbidity

Secondary outcome measures

Not provided at time of registration

Overall study start date

22/04/1994

Completion date

01/01/1998

Eligibility

Key inclusion criteria

1. Newly-diagnosed superficial carcinoma of bladder suitable for complete endoscopic resection, limited to the bladder
2. World Health Organisation (WHO) status zero to two
3. Expected survival at least three years
4. No history of other malignant tumours, except non-melanomatous skin tumours, or carcinoma in-situ (CIN)
5. No untreated urinary tract infection (UTI)

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

800

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

22/04/1994

Date of final enrolment

01/01/1998

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