

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	☐ Prospectively registered ☐ Protocol
Registration date 28/02/2001	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 13/02/2018	Condition category Cancer	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

Local recurrence, time to progression, metastases, morbidity

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

England

Study participating centre

MRC Clinical Trials Unit

London

United Kingdom

NW1 2DA

Sponsor information

Organisation

Medical Research Council (MRC) (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration