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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

Study design
Randomised controlled trial

Primary study design
Interventional

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, 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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes