ISRCTN77353795 https://doi.org/10.1186/ISRCTN77353795

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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 28/02/2001	**Overall study status** Completed	
Last Edited 13/02/2018	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Danielle Andrews

Contact details
MRC Clinical Trials Unit
222 Euston Road
London
United Kingdom
NW1 2DA

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
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
clinical.trial@headoffice.mrc.ac.uk

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