ISRCTN57776460 https://doi.org/10.1186/ISRCTN57776460

A randomised trial of intravesical thiotepa versus no intravesical chemotherapy

Submission date 13/03/2001	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 13/03/2001	**Overall study status** Completed	
Last Edited 11/09/2007	**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

Protocol serial number
BS01

Study information

Scientific Title

Study objectives
1. To detect any effect of intravesical instillation of Thiotepa on the recurrence rate of superficial bladder cancer

2. To detect any extra effect of repeating instillations of Thiotepa at follow-up cytoscopy during the first year on the recurrence rate of superficial bladder cancer
3. To assess the effect of the presence of urothelial atypism or carcinoma in random biopsies on the recurrence rate of superficial bladder cancer

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)
Not Specified

Health condition(s) or problem(s) studied
Cancer

Interventions
Intravesical thiotepa versus no intravesical chemotherapy

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Time to first superficial
2. Recurrence rate (number of positive cytoscopies per annum)
3. Failure-free survival rate

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/1991

Eligibility

Key inclusion criteria
1. Newly diagnosed superficial carcinoma of the bladder suitable for complete endoscopic resection
2. World Health Organisation (WHO) performance status 0-2
3. Expected survival at least 3 years

4. White count >3 x 10^9/L and platelets >100 x 10^9/L
5. No history of other malignant tumours
6. No untreated urinary tract infection

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
01/10/1981

Date of final enrolment
31/12/1991

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 (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/06/1994		Yes	No