

A randomised trial of intravesical thiotepa versus no intravesical chemotherapy

Submission date 13/03/2001	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/03/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 11/09/2007	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 cystoscopy 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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet**Health condition(s) or problem(s) studied**

Cancer

Interventions

Intravesical thiotepa versus no intravesical chemotherapy

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/10/1981

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 $>3 \times 10^9/L$ and platelets $>100 \times 10^9/L$
5. No history of other malignant tumours
6. No untreated urinary tract infection

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

417

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

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
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+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 (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

Study outputs

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