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Audit/research project for follow-up cystoscopy superficial bladder cancer

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/10/2019	Cancer	[ ] 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
SUPBLACAN

Study information

Scientific Title
Audit/research project for follow-up cystoscopy superficial bladder cancer

Study objectives
1. To conduct an audit of a new programme of cystoscopic follow-up for patients with Ta. T1 bladder carcinoma.
2. To conduct a randomised comparison of:

2.1. Mitocytin-C versus epirubicin as single intravesical instillations at the time of diagnosis to evaluate relative efficacy in prevention of recurrent bladder cancer
2.2. A single instillation of intravesical chemotherapy (MMC or Epi) versus five instillations (to be given at the time of each follow-up cystoscopy for 1 year) to determine the relative efficacy in reducing tumour recurrence in medium risk Ta.T1 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

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Cancer (neoplasms): Bladder (superficial)

Interventions
Not provided at time of registration

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Mitocytin-C versus Epirubicin

Primary outcome(s)
1.1 Number of unplanned incidents (return with symptoms, need for unscheduled cystoscopies or tumour resections).
1.2 Tumour recurrence rate and number of patients progressing to muscle invasion at 2 years.
iii. Inter-hospital variation of type of cystoscopy, anaesthetic, out-patient, day case, in-patient mix and cost of same.
2. Recurrence rate and progression to muscle invasion at 2 years.

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

Completion date
15/05/1997

Eligibility

Key inclusion criteria
Not provided at time of registration

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
16/05/1994

Date of final enrolment
15/05/1997

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
Newcastle
United Kingdom
NE7 7DN

Sponsor information

Organisation
NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration