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

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

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
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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
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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
16/05/1994

Completion date
15/05/1997

Eligibility

Key inclusion criteria
Not provided at time of registration

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Freeman Hospital
Newcastle
United Kingdom
NE7 7DN

Sponsor information

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

Sponsor details
The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
NHS Executive Northern and Yorkshire (UK)

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