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

Contact name

Mr R Hall

Contact details

Freeman Hospital Newcastle United Kingdom NE7 7DN

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

Study outputs

Output type Date created Date added Peer reviewed? Patient-facing? **Details** Participant information sheet 11/11/2025 11/11/2025 No

Participant information sheet Yes