

The use of fibreoptic bronchoscopy in improving the outcome of surgery in patients with upper gastrointestinal (GI) cancer

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/04/2015	Condition category Cancer	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N0025121734

Study information

Scientific Title

The use of fibreoptic bronchoscopy in improving the outcome of surgery in patients with upper gastrointestinal (GI) cancer

Study objectives

The use of fibreoptic bronchoscopy in improving the outcome of surgery in patients with upper GI 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)

Treatment

Health condition(s) or problem(s) studied

Cancer: Gastrointestinal

Interventions

Group 1: Postoperative awake flexible bronchoscopy will be carried out on ITU on days 1 and 2. Continuous monitoring of respiratory rate, heart rate, peripheral blood oxygen saturation and arterial blood pressure will be carried out during bronchoscopy. Equipment and expertise for endotracheal intubation will be available and used if patients experience significant deterioration in cardiovascular or respiratory function during procedure. All major and segmental bronchi will be inspected, toileting will be performed with suction and lavage. Protected brush samples taken for microbiology and semiquantitative analysis of specimens performed. In case of extensive secretions bronchoscopy will be repeated after day 2 as required. During procedure incidence of early postextubation injury to larynx, incidence of iatrogenic trauma to distal airways and recurrent laryngeal nerve injury also assessed. Photographs recorded during bronchoscopy. Postprocedure lung function - forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) ratio and peak flow will be assessed by spirometry and peak flow meter on days 1, 3, 5 and 8. Arterial blood gas analysis done days 1, 3 and 5. Temperature recorded daily. White cell count recorded days 1, 3 and 5.

Group 2: Best conventional treatment including epidural analgesia, humidified oxygen by mask and regular physiotherapy to clear secretions. Bronchoscopy will be undertaken in controlled subjects if clinically indicated.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/03/2005

Eligibility**Key inclusion criteria**

80 adult patients with upper GI cancer

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/03/2003

Date of final enrolment

01/03/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

University Hospital Aintree

Liverpool

United Kingdom

L9 7AL

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

Aintree Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration