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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 15/04/2015	**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

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

Primary study design
Interventional

Study design
Randomised controlled trial

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 brudh 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