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Routine quantitative microbiological screening in ventilated patients with, or at risk of, ALI /ARDS: effects on survival and long-term morbidity

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 08/02/2012	**Condition category** Respiratory	

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
N0265109355

Study information

Scientific Title

Study objectives
Does routine quantitative culture of BronchoAlveolar Lavage (BAL) improve delivery of care and functionally important outcomes in Acute Lung Injury (ALI)/Acute Respiratory Distress Syndrome (ARDS)?

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)
Screening

Health condition(s) or problem(s) studied
Respiratory: Acute Respiratory Distress Syndrome (ARDS) + Acute Lung Injury (ALI)

Interventions
1. Identify patients suitable for inclusion into study
2. Seek consultant assent (not one of the investigators) to enter patient into study
3. Randomise to quantitative or non-quantitative culture
4. Day one to two BronchoAlveolar Lavage (BAL) and peripheral blood sample (50 ml arterial blood, 5 ml venous blood)
5. Day four to six BAL and blood (l0 ml)
6. Day seven to nine BAL and blood (l0 ml)
7. Day 12 to 14 BAL and blood (l0 ml)
8. Weekly BAL and blood sampling thereafter. Sampling protocol based on evidence which shows that approximately 80% of episodes of Ventilator-Associated Pneumonia (VAP) occur in the first two weeks of invasive ventilation (Markowicz P, Wolff M, Djedaini K, et al: Multicenter prospective study of ventilator-associated pneumonia during ARDS. Am J Respir Crit Care Med 2000, 161:1942-1948).
9. Retrospective consent to take part in study, and to use retained specimens for research. Several models of consent have been applied to patients receiving intensive care. All, however, contain difficult issues regarding the competency of these patients to give informed consent at the proposed point of enrolment into the study. Following discussion with Dr C Counsell (R&D Support), we propose that Bronchoscopy/BAL is in the best interests of patients as it provides the best method of obtaining samples for microbiological analysis from the lungs of ventilated patients. Furthermore, BAL would form part of the routine investigative work-up for patients suspected of having VAP. In addition, BAL is recommended in severe ALI/ARDS to exclude sepsis prior to the commencement of systemic corticosteroids (Meduri GU, Chinn AJ, Leeper KV et al: Corticosteroid rescue treatment of progressive fibroproliferation in late ARDS: patterns of response and predictors of outcome. Chest 1994, 105:1516-1527). Therefore, informed consent for inclusion into the study, storage of patient data and storage of biological specimens for subsequent analysis will be sought retrospectively from patients after recruitment. Patients will also be asked to provide consent to attend a three month post-Intensive Care Unit (ICU) follow

up clinic for assessment of functional outcomes and health status
10. Survivors: Follow-up research clinic at three months at Wellcome Clinical Research Facility (CRF)
a. Health questionnaires
b. Full Pulmonary Function Tests
c. Shuttle walk
d. Bronchoscopy and BAL
11. Further follow-up at 12 months for quantitative density mask analysis of High Resolution Computed Tomography (CT) Thorax if suspected residual pulmonary fibrosis or bronchiectasis from 9., above. This would be my standard clinical management if I saw these patients in Out-Patients Department (OPD) at follow up

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
24/04/2008

Eligibility

Key inclusion criteria
1. Aged over 16 years
2. Patient receiving mechanical ventilation
3. Existence of, or risk factors for, ALI/ARDS

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

Key exclusion criteria
1. Pregnancy
2. Patient already enrolled in another interventional study
3. Little chance of survival, defined by Simplified Acute Physiologic Score II (SAPS II), over 65

points corresponds to predicted mortality in excess of 77%
4. Contraindication to bronchoscopy at enrolment

Date of first enrolment
24/04/2002

Date of final enrolment
24/04/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Respiratory Medicine
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Department of Health (UK)

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	safety and tolerability results	01/04/2005		Yes	No