

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/02/2012	<b>Condition category</b> Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**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**  
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

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Screening

## 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

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 measure**

Not provided at time of registration

## **Secondary outcome measures**

Not provided at time of registration

## **Overall study start date**

24/04/2002

## **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

**Age group**

Adult

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**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**

England

United Kingdom

**Study participating centre**

**Respiratory Medicine**

Birmingham

United Kingdom

B15 2TH

**Sponsor information**

## Organisation

Department of Health (UK)

## Sponsor details

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

## Sponsor type

Government

## Website

<http://www.doh.gov.uk>

## Funder(s)

### Funder type

Government

### Funder Name

University Hospital Birmingham NHS Trust (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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	safety and tolerability results	01/04/2005		Yes	No