

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/02/2012	Condition category 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

Contact name

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Contact details

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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 (10 ml)
6. Day seven to nine BAL and blood (10 ml)
7. Day 12 to 14 BAL and blood (10 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?
Results article	safety and tolerability results	01/04/2005		Yes	No