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A comparison of high rate, low tidal volume ventilation and conventional ventilation in the management of acute lung injury (ALI) and acute respiratory distress syndrome (ARDS)

Submission date
30/09/2004

Recruitment status
Stopped

Registration date
30/09/2004

Overall study status
Stopped

Last Edited
13/09/2012

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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
N0436125551

Study information

Scientific Title

Study objectives
Primary aim of the study is to show that there is an increase in ventilator free days in first 28 days using high respiratory rate, low tidal volume ventilation technique compared to standard ventilation techniques.

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
Acute respiratory distress

Interventions
Randomised controlled trial. Random allocation to:
1. New Treatment - high respiratory rate, low tidal volume ventilation
2. Standard Treatment - conventional ventilation

13/09/2012: Please note that this trial was stopped due to a lack of participants.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Ventilator free days in first 28 days
2. Reduced production of IL-6, IL-8 IL-10 Neutrophil count and tumour necrosis factor (TNF) in response to ventilation

Key secondary outcome(s)
Not provided at time of registration

Completion date

01/11/2004

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Patients intubated and receiving mechanical ventilation who have an acute decrease in ratio of partial pressure of arterial oxygen to fraction of inspired oxygen reaching the criteria for ALI and ARDS set by the American-European consensus conference committee

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/11/2002

Date of final enrolment
01/11/2004

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Anaesthetics Department
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration