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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	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2004	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 13/09/2012	**Condition category** Respiratory	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr H Buglass

Contact details
Anaesthetics Department
Chancellor Wing
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF
+44 (0)113 243 3144
r&d@leedsth.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/11/2002

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

Study participating centre
Anaesthetics Department
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds Teaching Hospitals 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