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)

Recruitment status	Prospectively registered
Stopped	☐ Protocol
Overall study status	Statistical analysis plan
Stopped	☐ Results
Condition category	Individual participant data
Last Edited Condition category 13/09/2012 Respiratory	Record updated in last year
	Stopped Overall study status Stopped Condition category

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr H Buglass

Contact details

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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