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A multicentre, randomised, double-blind, placebo-controlled trial to evaluate intravenous infusion of salbutamol versus saline for 28-day mortality in patients with acute respiratory distress syndrome

Submission date 14/04/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 07/07/2006	**Overall study status** Completed	
Last Edited 16/09/2013	**Condition category** Respiratory	

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
Version 2

Study information

Scientific Title

Acronym
BALTI-2

Study objectives
In patients with acute respiratory distress syndrome (ARDS), treatment with intravenous salbutamol will reduce 28-day mortality

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands Multicentre Research Ethics Committee, approval pending as of 01/05/2006

Study design
Randomised, double-blind, placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute respiratory distress syndrome

Interventions
Salbutamol or placebo will be administered through a dedicated intravenous line for seven days

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Salbutamol

Primary outcome(s)
Mortality 28 days after randomisation

Key secondary outcome(s))
1. Number of ventilator-free days
2. Mortality at (first) discharge from ICU
3. Mortality at discharge from hospital
4. Mortality at 12 months post randomisation

5. ICU length of stay
6. Hospital length of stay
7. Disability and quality of life at 12 months after randomisation

Completion date
01/09/2007

Eligibility

Key inclusion criteria
On day 1 following intensive care unit (ICU) admission, the primary caring ICU clinician should consider all adult patients (age ≥18 years) with severe hypoxaemic respiratory failure (PaO2 /FiO2) ≤26.7 kPa to be eligible for inclusion in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnancy
2. Cardiogenic pulmonary oedema (confirmed by medical history and chest x-ray)
3. Severe obstructive airway disease requiring nebulised or intravenous (IV) beta 2-agonists
4. Treatment with beta 2-blockers ≤48 hours
5. Brain stem death
6. Treatment withdrawal ≤24 hours, which indicates any interventions (including a trial) would be considered inappropriate
7. Refusing consent or patients in whom relatives refuse assent
8. Enrolled in another interventional clinical trial in the last 28 days

Date of first enrolment
01/08/2006

Date of final enrolment
01/09/2007

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Adult Intensive Care Unit
Birmingham
United Kingdom
B9 5SS

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

Funder(s)

Funder type
Research organisation

Funder Name
Intensive Care Society

Alternative Name(s)
The Intensive Care Society, ICS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/01/2012		Yes	No
Results article	results	01/09/2013		Yes	No
Protocol article	protocol	09/05/2011		Yes	No