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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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
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 measure
Mortality 28 days after randomisation

Secondary outcome measures
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

Overall study start date
01/08/2006

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

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
England

United Kingdom

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

Sponsor information

Organisation
Heart of England NHS Foundation Trust (UK)

Sponsor details
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
England
United Kingdom
B9 5SS

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Research organisation

Funder Name
Intensive Care Society

Alternative Name(s)
ICS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
United Kingdom

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?
Protocol article	protocol	09/05/2011		Yes	No
Results article	results	21/01/2012		Yes	No
Results article	results	01/09/2013		Yes	No