

# 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

<b>Submission date</b> 14/04/2006	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 07/07/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/09/2013	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

**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  $\geq 18$  years) with severe hypoxaemic respiratory failure ( $\text{PaO}_2/\text{FiO}_2$ )  $\leq 26.7$  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  $\leq 48$  hours
5. Brain stem death
6. Treatment withdrawal  $\leq 24$  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?
<a href="#">Protocol article</a>	protocol	09/05/2011		Yes	No
<a href="#">Results article</a>	results	21/01/2012		Yes	No
<a href="#">Results article</a>	results	01/09/2013		Yes	No