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

Recruitment status

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14/04/2006

No longer recruiting

[X] Protocol

Registration date

Overall study status

Statistical analysis plan

[X] Prospectively registered

07/07/2006

Completed

[X] Results

Last Edited 16/09/2013

Condition category

Respiratory

Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Fang Gao

Contact details

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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)

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

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 (PaO2 /FiO2) \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 ≤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)

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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