

The effect of a protective ventilation strategy, fine tuned using pulmonary mechanics monitoring, on outcome from severe acute respiratory failure in children

Submission date 12/09/2003	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/09/2009	Condition category Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

N0012027897

Study information

Scientific Title

Study objectives

Does the use of pulmonary function testing to adjust ventilation parameters improve outcome from acute paediatric respiratory failure?

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

Respiratory: Acute paediatric respiratory failure

Interventions

Please note that as of 16/09/09 the status of this record was changed to "Stopped" due to lack of funding. There is no plan to recommence the trial.

Randomised controlled trial. Random allocation to (A) Pulmonary function testing (B) Standard care.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Survival at 28 days.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/03/1999

Completion date

24/05/2003

Reason abandoned (if study stopped)

Lack of funding/sponsorship

Eligibility

Key inclusion criteria

Children with severe acute respiratory failure.

Participant type(s)

Patient

Age group

Child

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/03/1999

Date of final enrolment

24/05/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
PICU
London
United Kingdom
WC1N 3JH

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
<http://www.doh.gov.uk>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Great Ormond Street Hospital for Children NHS Trust / Institute of Child Health (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