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A study of early continuous positive airway pressure in acute respiratory failure in children with impaired immunity

Submission date
19/10/2012

Recruitment status
No longer recruiting

Registration date
14/11/2012

Overall study status
Completed

Last Edited
22/07/2020

Condition category
Respiratory

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Mild breathing difficulties are common in children with weakened immunity. However, if a child develops severe breathing difficulties, this can result in damage to the lungs to the point where they no longer function properly and the child requires support from a special machine called a mechanical ventilator, which breathes for them. Currently, if a child develops severe breathing difficulties, they are treated on the ward with oxygen, antibiotics and careful control of fluids. If, despite this treatment, their breathing difficulties get worse, they will usually be admitted to the intensive care unit for further treatment. This often involves the child receiving a general anaesthetic to allow them to be attached to a mechanical ventilator to help them breathe. Recent studies in adults with impaired immunity have shown that it might be better to admit patients to the intensive care unit earlier, before their breathing problems get worse, for a treatment called continuous positive airway pressure (CPAP). CPAP is a technique for keeping lungs well inflated by the use of gentle air pressure via a face mask. In theory, holding the lungs open a little more with the extra pressure of CPAP should make the effort of breathing less, and reduce the risk of further chest infections. Patients in the studies who received CPAP early were less likely to need a general anaesthetic and mechanical ventilation. However, these studies only involved small numbers of patients who were all adults. More research is needed which also includes children. We do not know if early treatment with CPAP is better, so the purpose of this study is to find out if early admission to the intensive care unit for CPAP results in more children recovering from severe breathing difficulties compared to usual treatment.

Who can participate?
Children aged less than 18 years who are being treated at participating hospitals, with weakened immunity and severe breathing difficulties.

What does the study involve?
If a child is assigned to the CPAP group, he/she will be admitted to the intensive care unit and have CPAP delivered via a face mask for a minimum of 12 hours per day for at least four consecutive days. After this, the child will receive usual treatment as directed by the medical team which may or may not include continuing with CPAP. The child will be monitored closely by

the medical team. If a child is assigned to the usual treatment group, he/she will continue to receive treatment on the ward, including oxygen therapy, antibiotics and fluids. The child will be monitored closely by the medical team. If the child requires more intensive treatment, he/she will be admitted to the intensive care unit in accordance with standard acutely ill child protocols and as deemed necessary by the ICU outreach/medical rapid response teams and the clinical team responsible for the childs care.

What are the possible benefits and risks of participating?
Participants will be playing an important part in finding out what is the best way to help young people like them to get better. We cant promise this research will help children, but they will be helping others just like them who have the same problems in the future. All medical procedures, regardless of study participation, involve some risk of injury. We are doing this study because we do not know if early admission to the intensive care unit for CPAP is better than continuing treatment on the ward. Delivery of CPAP requires the child to wear a moderately tight-fitting face mask and it is possible that they may not feel comfortable with the face mask on. However, most children with severe breathing difficulties recognise very quickly that once the face mask is in position that breathing is much easier. If a child does find the face mask difficult to tolerate, the medical team will make a decision about whether to try gentle sedation to assist with the CPAP or to leave the face mask off. If the face mask is used for many days there is a risk of areas of skin becoming sore where the face mask is in contact with the skin, particularly on the bridge of the nose. This risk can usually be minimised by giving rest periods off the CPAP mask or by changing the mask shape from time to time.

Where is the study run from?
The study will take place at four NHS hospitals in the UK and is being managed by the Intensive Care National Audit & Research Centre (ICNARC).

When is the study starting and how long is it expected to run for?
The study will run from January 2013 to January 2016.

Who is funding the study?
The study is being funded by the Great Ormond Street Hospital Childrens Charity, Registered Charity No 235825.

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10AR31

Study information

Scientific Title
Randomised Study of early Continuous positive airway pressure in Acute Respiratory Failure in children with impaired immunity

Acronym
SCARF

Study objectives
Early admission to the paediatric intensive care unit (PICU) for delivery of continuous positive airway pressure (CPAP) will reduce the need for intubation and invasive mechanical ventilation within 30 days and improve survival from both acute and acute on chronic respiratory failure in children with impaired immunity.

On 07/07/2014 the following changes were made to the trial record:
1. The study design was changed from 'Single centre pragmatic open randomised controlled trial' to 'Multi-centre pragmatic open randomised controlled trial'
2. The anticipated start date was changed from 09/11/2012 to 01/01/2013
3. The anticipated end date was changed from 08/11/2016 to 01/01/2017

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Riverside, 13/08/2012, ref: 12/LO/1051

Study design
Multi-centre pragmatic open randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 failure in immune impaired children

Interventions
Current interventions as of 07/07/2014:
Intervention group
Participants allocated to the intervention group will be admitted to the PICU and receive Continuous Positive Airway Pressure (CPAP) of at least 6 cm of water (PEEP) with supplemental oxygen for a minimum of 12 hours per day for at least four consecutive days. The interface for delivering CPAP (i.e. via face mask, helmet or infant flow-driver) will be at the discretion of the clinical team responsible for the patients care. All other care will be determined by the clinical team primarily responsible for the patients care.

Control group
Participants allocated to the control group will remain on the ward and receive supplemental oxygen to maintain oxygen saturation in accordance with standard local practice. All other care (including antimicrobial therapy, fluid therapy, analgesia and sedative agents, bronchodilator therapy) will be determined by the clinical team primarily responsible for the childs care. Participants in the control group will be admitted to the PICU in accordance with standard acutely ill child protocols and as deemed necessary by the ICU outreach/medical rapid response teams and the clinical team responsible for the childs care.

Previous interventions:
Intervention group
Participants allocated to the intervention group will be admitted to the PICU and receive Continuous Positive Airway Pressure (CPAP) of at least 6 cm H2O with supplemental oxygen for a minimum of 12 hours per day for at least four consecutive days. The interface for delivering CPAP (i.e. via face mask, helmet or infant flow-driver) will be at the discretion of the clinical team responsible for the patients care. All other care will be determined by the clinical team primarily responsible for the patients care.

Control group
Participants allocated to the control group will remain on the ward and receive supplemental oxygen to maintain oxygen saturation in accordance with standard local practice (Level 1 respiratory support see: Section 10.3). All other care (including antimicrobial therapy, fluid therapy, analgesia and sedative agents, bronchodilator therapy) will be determined by the clinical team primarily responsible for the childs care. Participants in the control group will be admitted to the PICU in accordance with standard Great Ormond Street Hospital acutely ill child protocols and as deemed necessary by the Intensive Care Outreach Network/Clinical Site Practitioner and the clinical team responsible for the childs care.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Requirement for intubation and invasive mechanical ventilation within 30 days post-randomisation

Secondary outcome measures
1. Maximum and aggregate daily organ failure score
2. Mortality at 30 days post-randomisation
3. Requirement for Level 2 or Level 3 respiratory support within 30 days post-randomisation
4. Days free from any ventilator support at 30 days post-randomisation
5. Days free from supplemental oxygen (i.e., above pre-acute respiratory failure requirement) at 30 days post-randomisation
6. Hospital mortality
7. Mortality at 90 days post-randomisation
8. Mortality 1 year post-randomisation

Overall study start date
01/01/2013

Completion date
01/01/2017

Eligibility

Key inclusion criteria
Current inclusion criteria as of 07/07/2014:
1. Age less than 18 years
2. Expected to have impaired immunity for at least 3 months as a result of a primary diagnosis, therapy or a combination of both
3. Acute respiratory failure or acute on chronic respiratory failure

Previous inclusion criteria:
1. Age less than 16 years
2. Expected to have impaired immunity for at least 3 months as a result of a primary diagnosis, therapy or a combination of both
3. Acute respiratory failure or acute on chronic respiratory failure

Participant type(s)
Patient

Age group
Child

Upper age limit
18 Years

Sex
Both

Target number of participants
148

Total final enrolment
114

Key exclusion criteria
1. Already receiving invasive mechanical ventilation for non-respiratory indications
2. Other acute indication for emergency PICU admission and invasive mechanical ventilation, independent of the degree of respiratory failure (e.g., shock, reduced level of consciousness, seizures), as assessed by the PICU team
3. Recent oesophageal/gastric surgery
4. End-of-life care plan in place with limitation of resuscitation
5. Life expectancy less than 12 months
6. Already receiving treatment on PICU

Date of first enrolment
01/01/2013

Date of final enrolment
01/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Reader in Paediatric Intensive Care and Hon Consultant Intensivist
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust (UK)

Sponsor details

Joint Research and Development Office
Division of Research and Innovation
NHS Foundation Trust & The UCL Institute of Child Health
2nd Floor, 30 Guilford Street
London
England
United Kingdom
WC1N 1EH

Sponsor type
Hospital/treatment centre

Website
http://www.gosh.org/

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Charity

Funder Name
Great Ormond Street Hospital for Childrens Charity (UK), ref: 235825

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?
Results article	results	01/10/2018	22/07/2020	Yes	No