



# Early CPAP for acute respiratory failure in children with impaired immunity

## Background

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Mild breathing difficulties are common in children with impaired immunity. If a child develops severe breathing difficulties, this can result in acute respiratory failure (where the lungs no longer function properly). This is characterised by pulmonary oedema, reduced lung compliance and hypoxaemia.

Currently, when a child develops severe breathing difficulties, they will be treated on the ward with oxygen, antibiotics and fluids. If, despite treatment, their breathing difficulties worsen, 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 which helps them breathe.

Overall fatality rates for these children approach 50%.

## Continuous positive airways pressure

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Continuous positive airways pressure (CPAP) is a technique for keeping the lungs well inflated by the use of gentle air pressure via a face mask or helmet. In theory, holding the lungs open a little more should reduce the effort of breathing, and subsequently reduce the risk of chest infections.

Recent randomised controlled trials of adults with impaired immunity and acute respiratory failure have suggested that using CPAP, before breathing difficulties worsen, reduces the risk of death by around 60%.

Patients in the studies who received CPAP early were less likely to need a general anaesthetic and mechanical ventilation. These studies only involved small numbers of patients who were all adults. More research is therefore needed to understand if CPAP is beneficial to children.

## What is SCARF?

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A pragmatic, randomised controlled trial in infants and children with severely impaired immunity and acute respiratory failure

## Aim

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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 when compared to usual treatment.

## Primary objective

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

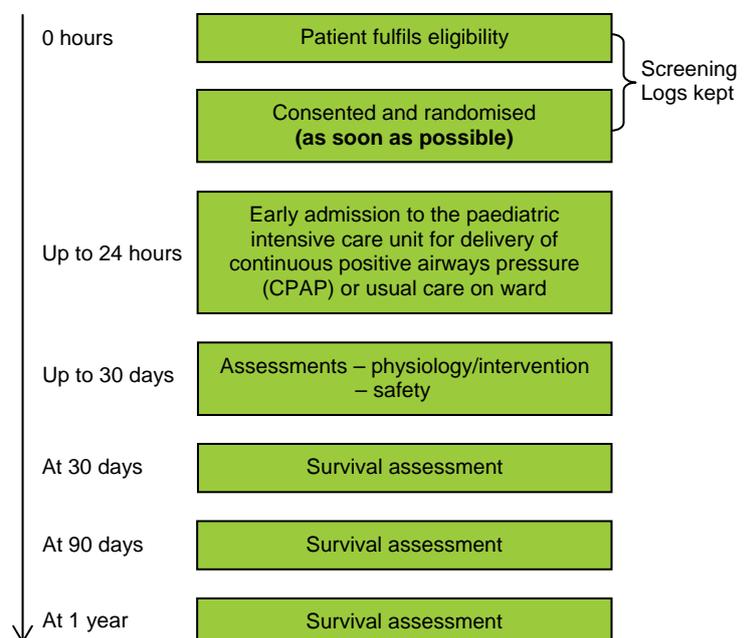
## Site/Patients

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- **Three paediatric NHS hospitals**
- **148 infants and children**  
(74 per arm)

## Timeline

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## Screening/Eligibility

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Infants and children who are receiving treatment on the ward must fulfil the following three inclusion criteria:

- age less than 18 years;
- severely impaired immunity (expected to have impaired immunity for at least three months as a result of a primary diagnosis, therapy or a combination of both);
- acute respiratory failure or acute on chronic respiratory failure.

## Consent/Randomisation

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As soon as the eligibility criteria are met, consent and randomisation should be completed as soon as possible, with the aim of commencing treatment within 24 hours.

Consent will be sought from the parent/guardian. Assent should be sought from children over 8 years of age (or if deemed appropriate).

Participants will either be randomised to:

- the intervention group – early admission to PICU for CPAP; or
- the control group – stay on the ward to receive usual treatment.

All other care will be at the discretion of the treating clinician.

## Funding

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Great Ormond Street Hospital Children's Charity, 10AR31

## Sponsor

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Great Ormond Street Hospital for Children NHS Foundation Trust

## Trial Management

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ICNARC Clinical Trials Unit

## Team

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## For further information

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