Oxy-PICU

Safety and feasibility of a clinical trial of permissive hypoxia in paediatric critical illness

What is this study about?

Around 19,000 critically ill children are admitted to paediatric intensive care units (PICU) each year in the UK. A large number of these children need breathing support, and this is usually provided through an invasive machine called a ‘ventilator’. Clinicians make decisions for treatment based on how much oxygen their patient has in their blood (this is called oxygen saturation or oxygenation) and currently the amount of oxygen critically ill children need is not fully understood. This means that some clinicians use a lower oxygen saturation target, and others, a higher target. This may be problematic as research in neonates (babies) and adults has shown that oxygen saturation levels can influence a patient’s chance of survival, how long they stay in hospital and healthcare costs.

Response to oxygen is different in babies, children and adults. This means that the results from both the neonatal and adult research are unlikely to be valid or applicable in children due to age-related differences. Urgent high quality clinical evidence is therefore needed to inform on the best targets of oxygen saturation during critical illness in children.

As large clinical trials are expensive to conduct, it is important to demonstrate that a large-scale trial can be done and that the different components of a trial can all work together. Therefore, the Oxy-PICU study is a ‘pilot randomised clinical trial’ (a smaller version of the trial we would like to conduct) and will test the feasibility and safety of conducting a large scale trial comparing restrictive oxygen saturations (88-92%) with a more liberal oxygen saturation (≥95%). Oxy-PICU will also collect blood and urine samples to allow for in-depth study of the biology of the different oxygen saturation targets.

The pilot trial will take place at three PICUs (two in London and one in Southampton) and aims to include between 115-125 eligible children over six months. Children are eligible if they:

- are admitted to one of the three PICUs following an emergency;
- receive invasive mechanical ventilation; and
- are expected to need ventilation for 24 hours or more.

Given the emergency nature of these children and the need to provide immediate care, informed consent will be sought after the children are entered into the study (this is known as deferred consent).

When is it taking place?

1 September 2016 to 31 August 2017
Who is leading the study?

Professor Mark Peters, Great Ormond Street Hospital for Children NHS Foundation Trust

Who is funding the study?

Great Ormond Street Hospital Children’s Charity