



If you have any questions  
about Oxy-PICU,  
you can speak to a member of the  
Oxy-PICU team in this unit:

*Katarzyna Swist-Szulik*

Research Nurses

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Thank you for taking the time  
to read this leaflet.

Please see the main  
Participant Information Sheet  
(Parents or Guardians)  
for full details of the study.

East of England - Cambridge South  
Research Ethics Committee

Reference Number: 19/EE/0362

IRAS Number: 272768

Participant Information Leaflet  
(Parents or Guardians)

v1.1, 7th August 2020



Manchester University  
NHS Foundation Trust



This unit is participating in the

## Oxy-PICU trial

A research study about  
oxygen treatment for children  
in intensive care



## What is the purpose of the study?

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Breathing problems are the most common reason for a child to need an emergency admission to intensive care. Extra oxygen given through a ventilator (breathing machine) is often a vital part of their treatment. There have been huge safety improvements in ventilator use over the last 25 years. We now use ventilators more gently meaning the lungs are much less likely to be injured.

Doctors and nurses adjust the oxygen given based on how much oxygen there is in the blood, known as oxygen saturation. We know that very low oxygen saturations are harmful but we think very high saturations may also be harmful.

This study aims to find out whether aiming for a slightly lower oxygen saturation when treating children on a ventilator is better than a very high oxygen saturation. This will help improve the future treatment of children in intensive care. We monitor the study closely and, if one treatment is better or worse, we will stop the study.

## What will happen?

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Breathing support is usually started during an emergency where treatment decisions must be made quickly. The clinical team will enrol children into the study and focus on delivering the treatment, and then inform parents or guardians as soon as possible after. This is called the 'deferred consent model' and is often used in this type of study.

Children in the study will be randomly put into to one of two groups by a computer. One group will receive treatment aiming for blood oxygen saturations above 94%, and the other at 88-92%. The doctors and nurses will change the ventilator settings and amount of oxygen given to keep oxygen saturations within these ranges. Both ranges are within recommended guidelines.

All other aspects of care are the same and follow usual practice. All children in the study will be monitored closely. The clinical team can stop a child participating if it is best for them.

## What information will be collected?

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We will collect information on each child's progress from their medical notes and the national databases of NHS patient records. . One year later, the Intensive Care National Audit & Research Centre will send a short questionnaire to parents and guardians to find out how their child is doing. All information collected will be kept secure and confidential at all times.

## Does my child have to take part?

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If your child is eligible, joining the study is entirely voluntary. You are free to leave the study at any time and this will not affect the standard of care you or your child receives.

## What next?

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You may be approached about this study by a member of the research team. An information sheet will be provided and a member of the team will go through this in detail with you.