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

Dr Graham Mason

Rebecca Marshall or Claire Jennings
(Research Nurses)

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.

Research Ethics Committee
Reference Number: 19/EE/0185

IRAS Number: 260536

Participant Information Leaflet
(Parents or Guardians)

v1.1, 18 June 2019

NHS
Manchester University
NHS Foundation Trust

FIRST ABC

FIRST-line support for
Assistance in Breathing in Children

Great Ormond Street Hospital for Children NHS
NHS Foundation Trust

icnarc intensive care national audit & research centre

What is the purpose of the study?

Breathing support is the most common treatment provided to unwell children in the intensive care unit or high dependency unit.

Non-invasive breathing support is mainly used to help prevent a child from needing to be put onto a breathing machine (ventilator) or from going back onto a ventilator after coming off one. There are two main ways or providing non-invasive breathing support - these are called Continuous Positive Airway Pressure (CPAP) and High Flow Nasal Cannula (HFNC).

Both methods are widely used across the NHS to provide non-invasive breathing support, however it is not currently clear if one should be used over the other, as the first treatment option.

Our aim is to find out whether HFNC is as good as CPAP for children who need non-invasive respiratory support.

What will happen if I take part and what do I have to do?

Non-invasive breathing support is usually started during a time-sensitive situation where decisions about treatment need to be made very 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 method of consent is commonly used in this type of study.

Half of the children in the study will receive CPAP and the other half will receive HFNC. The children in the study would have received one of these types of support even if they were not in the study - the only difference is that the first treatment option will be chosen by the study, rather than the doctor.

All other aspects of care are the same and follow usual practice, irrespective of the breathing support chosen. All children in the study will be monitored closely and if they do not improve on the treatment, the doctors can decide to switch them over to the other treatment or use other forms of breathing support.

What information will be collected?

We will collect information regarding each child's progress from the medical notes in the hospital and in the national databases of NHS patient records. We will also ask the parents or guardians of children involved in the study about their experiences and reactions to being in the intensive care or high dependency unit. Six months later, the Intensive Care National Audit & Research Centre (ICNARC) will also send a short questionnaire to parents and guardians to find out how their child is doing.

All information collected is kept secure and confidential.

Do I have to take part?

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?

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.