FIRST-line support for Assistance in Breathing in Children

Participant Information Sheet (Parents or Guardian)

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We would like to invite you and your child to take part in a research study

Before you decide whether you and your child would like to participate in this study, it is important for you to understand why this research is being done and what it involves. You are free to decide whether or not you wish your child to be included in this study. Please take time to read the following information.

Please ask the nurse or doctor who has spoken or written to you about anything that is not clear, or if you would like more information. Talk to others about the study if you wish. Your decision will not affect the care your child will receive.

Your child needed breathing support while they were in the intensive care 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. Currently, there are two main methods of providing this type of support non-invasively. The first is called Continuous Positive Airway Pressure (CPAP). The CPAP method has been used for a long time and involves providing oxygen/air through the child's nose or through a face mask. The second method is called High Flow Nasal Cannula (HFNC). The HFNC method is newer and involves giving oxygen/air through tiny tubes inserted into the child's nostrils. Both methods have a similar effect on the lungs and are used across the NHS, with some hospitals using CPAP more often, and others, HFNC.

Why are we doing this study?

We are doing this study (FIRST-ABC: FIRST-line Assistance in Breathing in Children) to compare HFNC to CPAP when used as the first treatment option for non-invasive breathing support.

Breathing support is the most common treatment provided to children in the intensive care or high dependency unit. Even if the main problem is not with the lungs, breathing support is often a vital part of their treatment. The two main ways of providing non-invasive breathing support are CPAP and HFNC. Currently it is not clear which of these two methods should be used as the first treatment option for unwell children.

CPAP (Continuous Positive Airway Pressure) is a method that has been used for over 30 years. This method is quite effective – 4 out of 5 children get better on this treatment without needing further breathing support. However, some children find it uncomfortable and do not tolerate it.

HFNC (High Flow Nasal Cannula) is a newer method that has started to be used over the last 10 years. Less is known about how effective HFNC is when compared to CPAP, but some children appear more comfortable on HFNC.

Our aim is to find out whether HFNC is as effective as CPAP for children who need non-invasive breathing support in the intensive care or high dependency unit. It is not yet known if one method is better than the other or if one method is more suitable for more children.

This hospital is one of around 25 hospitals around the country that are taking part in FIRST-ABC. This is a large national study involving 1,200 children. We will monitor the study closely and, if it is clear that one treatment is better, or worse, we will stop the study.

Why has my child been chosen to take part in this study?

Your child was chosen to take part because the doctors and nurses decided that they needed non-invasive breathing support. We hope to include 1,200 children in the study.

What do I need to know about the treatments used in this study and the possible side effects?

Both methods are already widely used across the NHS to provide non-invasive breathing support. The only difference will be that the first treatment option will be chosen by the study rather than the doctor.

Your child will be monitored closely and if they do not improve on the treatment, your doctor can decide to switch them over to the other method or use other forms of breathing support if needed. Any complications will be managed in the same way as they would have been even if your child was not involved in the study. Your doctor will also decide when breathing support is no longer needed.

What are the risks or side-effects of the treatment that my child will receive?

No significant safety concerns about either treatment have been reported. However, as with all treatments there are risks of complications. With the CPAP (Continuous Airway Positive Pressure) method these include air leaking outside the lungs, vomiting from stomach bloating from the oxygen/air, and pressure sores on the nose or cheeks from the face mask, but these do not happen very often. With the newer HFNC (High Flow Nasal Cannula) method, these include pressure sores on the nose or cheeks from the tubing, again these do not occur very often.

If for any reason the doctors feel that your child has not improved as expected, they have the option to switch to the other method or use other forms of breathing support, minimising any risk of harm from involvement in the study. All other aspects of care, including medicines, will follow usual NHS practice and are not related to the study.

What are the benefits of taking part?

We cannot promise that your child will benefit directly by participating in this study. The benefits and risks of one method over the over are unclear at this time – which is why this research is needed. By answering this question, we will help to improve the care of future unwell children.

How was it decided which method of breathing support my child was started on?

FIRST-ABC is a 'randomised clinical trial' - which means that each child is randomly put into one of two groups:

- Children in Group 1 receive CPAP as the first option for treatment
- Children in Group 2 receive HFNC as the first option for treatment

To make sure it is fair, children are put into the groups at random by a computer programme (this is called randomisation). This means that your child had an equal chance of being in Group 1 or Group 2. Your child's progress has been closely monitored and they have received all other treatments they needed to give the best chance to recover from their illness.

What treatment would my child have received if the study was not taking place?

The first treatment option that your child would have received if they were not part of the study would still have been CPAP or HFNC, but the decision would have been made by your doctor instead of the study.

Why am I being asked after my child has started the treatment, rather than before?

As this was a time-sensitive situation, we could not delay starting the treatment your child needed. Explaining the study in advance would have caused a delay in giving your child urgent treatment. We have therefore come to talk to you about the study as soon as possible afterwards. This is called "research without prior consent", a method of consent used in similar studies.

Who is funding and organising the study?

The study is funded by the National Institute for Health Research, Health Technology Assessment Programme. Dr Padmanabhan Ramnarayan is the Chief Investigator (the person leading the study). The Great Ormond Street Hospital for Children NHS Foundation Trust are the Sponsor for the study. The Intensive Care National Audit & Research Centre (ICNARC) are managing the study. All are based in the United Kingdom.

The research team are qualified to do this study because they have all the specialties and skills needed, including caring for unwell children and doing health research. Parents of children who have experienced intensive care have been involved in developing of the study, including this information sheet and how you were asked to take part.

Do we have to take part?

No. Participation is **voluntary**. It is up to you and your child (wherever possible) to decide to join the study. We will explain the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a Consent Form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an Assent Form with you, if they want to.

If you decide that you do not want your child to be part of the research, then this will not affect the future care of you or your child.

What will happen next?

1. If you agree to continue in the study - ~~in addition to information already collected,~~ the hospital research team will continue to collect a few further anonymised items of information for FIRST-ABC about your child's treatments and progress during their hospital admission, as well as their survival until the end of the study. We'd also like to ask you a few questions about your feelings and reactions to being in the intensive care or high dependency unit, if you are willing. This information will be securely sent to the Intensive Care National Audit & Research Centre (ICNARC) who are managing the study and will analyse the results at the end of the study.

2. ~~To meet the objectives of the study, i~~If you agree, the hospital research team will also send identifiable information about your child to ICNARC, so that they can follow-up on your child's well-being by requesting some important health information (survival) from the national database of patient records maintained by NHS Digital. To do this, ICNARC will securely send your child's name, date of birth, postcode and NHS number to NHS Digital (these pieces of information are needed to ensure that your child is identified in the database correctly). NHS Digital will then securely provide the important health information (survival) back to ICNARC. All information will be stored securely and only be accessed by authorised people. Information from these databases is used to support many research studies and there are strict controls in place to ensure confidentiality.

3. Then, after six months, we would like to contact you with a short questionnaire to find out how your child is doing. The questionnaire takes around 15 minutes to complete and can be sent to you by email or post (whichever you prefer). We may telephone you a few weeks later to see if you received it. If you agree, we will pass your name and contact details onto ICNARC who will send you the questionnaire.

4. Information collected from research studies can be used to address many important research questions beyond those planned in the original study. This has the potential to provide real benefit to patients, the NHS and the scientific community. If possible, we would like your permission to share anonymised information about your child with other approved researchers if we feel it could contribute to answering other important health questions. Examples of anonymised data would include your child's age, what treatments they were given or how long they were in hospital. The other researchers would not be able to identify you or your child.

5. We would also like to ask for your permission to contact you about any future related research studies where we feel your views and opinions would be valuable (for example, to take part in an interview discussing a new research study related to intensive care). If you agree to this option, we will keep your contact details for up to five years after the end of the study.

All of the options listed above are voluntary and you can change your mind at any time. If you agree to any of them, we will ask you to sign a Consent Form. To leave the study at any point, you can either contact the Principal Investigator or Research Nurse (the doctor and nurse leading the study at this hospital) using the details on the last page of this leaflet or by contacting ICNARC by phone on 020 7269 9277 or email to firstabc@icnarc.org.

Will the information be kept confidential?

Yes. We will follow the law (Data Protection Act 2018) by making sure your information is kept private and secure.

How will my child's information be used and what are my choices about how it is used ~~will happen to it~~?

Both Great Ormond Street Hospital for Children NHS Foundation Trust and the Intensive Care National Audit & Research Centre (ICNARC) are the data controllers for the study and are responsible for looking after yours and your child's information and using it properly. The [Local NHS Trust] will collect information from you and your child's medical records for this research study in accordance with our instructions (as described earlier) and will pass this onto ICNARC.

~~If you agree, this information will include their name, NHS number, date of birth and relevant health information, which is regarded as a special category information.~~ People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your or your child's name or contact details. Your data will have a code number instead.~~ICNARC will use the information from your child's medical records in order to manage the study and find out whether HFNC is as effective as CPAP.~~ Once we have finished the study, we will keep some of the data so we can check the results.

ICNARC will keep identifiable information about you and your child for no longer than one year after it is finished ~~the study has finished~~ (unless you have agreed otherwise). ~~and the rest of the research data will be kept for up to 15 years. [Local NHS Trust] will keep identifiable information about your child from this study for fifteen years after the study has finished. All information will be stored securely. Great Ormond Street Hospital for Children NHS Foundation Trust will not receive [new] identifiable information about you or your child that has emerged from this study.~~

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you or your child. You can stop being part of the study at any time, without giving a reason, but we will keep information about you and your child that we already have. ~~The [Local NHS Trust] and ICNARC will use your name and contact details to contact you about the study (including the questionnaire), to make sure that relevant information about the study is recorded for your child's care, and to oversee the quality of the study. Individuals from ICNARC and regulatory authorities may look at your child's medical and research records to check the accuracy of the study. The only people from ICNARC who will have access to information that identifies you or your child will be those who will need to contact you about the questionnaire or audit the data collection process. The people who analyse the information will not be able to find out yours or your child's name, NHS number or contact details.~~ If you decline participation, the study will keep information on treatments and procedures that happened up to when you made your decision (unless you don't wish us to) but no information about treatments and procedures after your decision will be included. Similarly, if you later choose to stop taking part in the study, we will keep the information on events that already happened up to your decision.

Where can you find out more about how your information is used?

You can find out more about how we use your information;

- at www.hra.nhs.uk/information-about-patients/
- at www.icnarc.org/Our-Research/Studies/FIRST-ABC
- by asking one of the research team
- by sending an email to firstabc@icnarc.org
- ~~Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard you and your child's rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at:~~

~~www.icnarc.org/Our-Research/Studies/FIRST-ABC~~

What will happen to the results of this study?

The results of the study will be published in scientific journals. You will be able to find the results on ICNARC's website (www.icnarc.org) within a year after the study is completed. We will write our reports in a way that no-one can work out who took part in the study.~~It will not be possible to identify any person who has taken part in the study in any reports or articles.~~

What if there is a problem?

Complaints: If you have a concern about any aspect of FIRST-ABC, you should ask to speak with the Principal Investigator <Insert NAME> or research team at your hospital who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or the Patient Advisory Liaison Service (PALS), contactable on <Insert PALS number>. You may also have the right to lodge a complaint with the Information Commissioner's Office (ICO) (www.ico.org.uk).

Harm: It is very unlikely that any participants in this research will come to any harm, but we are obliged to mention this possibility. If something does go wrong, and your child is harmed during the study and this is due to the design of the study or someone's negligence then you may have grounds for a legal action for compensation against Great Ormond Street Hospital for Children NHS Foundation Trust, but you may have to pay your legal costs. The normal NHS complaints mechanisms will be available to you.

Who has reviewed the study?

All NHS research is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. FIRST-ABC was reviewed by the East of England - Cambridge South Research Ethics Committee who approved the study and agreed it is being conducted in a correct and appropriate manner.

Important things that you need to know

- Your child needed non-invasive breathing support during a time-sensitive situation and it was important that we treated them as quickly as possible.
- Both CPAP and HFNC are widely used all across the NHS, but it is not clear which one should be used as the first treatment choice.
- As this was a time-sensitive situation, your child has already been started on either HFNC or CPAP as part of the study. They would have been started on one of these treatments even if they were not involved in the study. Your child will be monitored closely and the clinical team will change treatment if needed.
- This type of research is called 'research without prior consent' and is done in time-sensitive situations when comparing treatments to find out which is best. We are now asking for your consent to continue participation in FIRST-ABC.

We are very grateful that you are considering taking part in this study - thank you very much for your time.

If you have any questions, please contact:

Principal Investigator	**Research Nurse**
Name:	Name:
Telephone:	Telephone: