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The PRESSURE Study

PRotocolised Evaluation of permiSSive blood pressure targets versus Usual care (PRESSURE)

Participant Information Sheet (Parents or Guardians)

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

- Please take time to read this information and decide whether you wish for your child to continue in this research study. Discuss it with friends and relatives if you wish.
- There is also a **video** you can watch about the study (see QR code below).
- You are free to decide whether your child's information is included in the research.
- Your child can stop taking part in the study at any time, without you giving a reason.
- Ask us if anything is not clear or if you would like more information.
- If you agree for your child to continue to take part, you will be asked to sign a Consent Form. You will be given a copy of the signed form for your records.

Scan the QR code to watch a video about the study, or watch it via the PRESSURE study website: www.icnarc.org/research-studies/PRESSURE

Important things you need to know:

- Your child required medication to increase their blood pressure. These medications are the standard treatment and usual treatment is to aim at a "normal blood pressure for age".
- Until now no trials have been done to look at blood pressure targets in children in intensive care.
- We want to find out whether reducing the amount of blood pressure medications your child receives, by aiming for a blood pressure at the lower end of the normal range, is better than usual treatment.
- Your child came to intensive care in an emergency and needed urgent treatment. Because of this, your child has been included in the study and may have already been treated using a lower blood pressure target or continued to receive the usual treatment. Both the lower and usual target blood pressure targets are within the normal range for your child.
- This type of research is called 'research without prior consent' and is done in emergencies when comparing treatments to find out which is best.
- We are now asking for your consent for your child to continue in the study.
- Your child's blood pressure is continuously monitored to ensure their blood pressure remains in a safe range.

Contents

1 Why are we doing this study?

We are doing this study to find out more about how low blood pressure (also known as hypotension) is managed and treated. This is common in children in intensive care.

If you want to know more about hypotension, please feel free to talk to the doctor or nurse who is treating your child (or who has now written to you if your child has already been discharged from hospital).

How is low blood pressure usually treated?

There are many treatments used in intensive care to increase blood pressure. These include drugs which make blood vessels narrow and make the heart pump harder ("vasoactive drugs"), but these treatments carry risks. Currently to guide these treatments, most doctors aim to achieve a blood pressure in the normal range for the child's age. However, currently there is no clear evidence to support this practice.

What are we trying to find out?

We want to find out whether children on intensive care could be managed more safely with lower blood pressure targets, still within the normal range. If this could be shown, it may be that these children could safely receive less drug treatment and they may recover more quickly.

We will include 1,900 children from 20 NHS paediatric intensive care units (PICUs) in the study. We will closely monitor the study and if one treatment is clearly better than the other, we will stop the study.

2 Why am I being asked for my child to take part?

You are being asked to take part in the PRESSURE study because while your child was looked after in the PICU they had low blood pressure and needed to be treated for it. They were suitable for this research study and have already been included in it.

3 Why am I being asked after my child has started the treatment?

As this was a medical emergency, we could not delay giving your child the urgent treatment to talk to you about this study at the time.

We have therefore come to talk to you about the study as soon as possible after the medical emergency. This is called "research without prior consent", a method of consent used in other emergency studies.

4 What happens in this study?

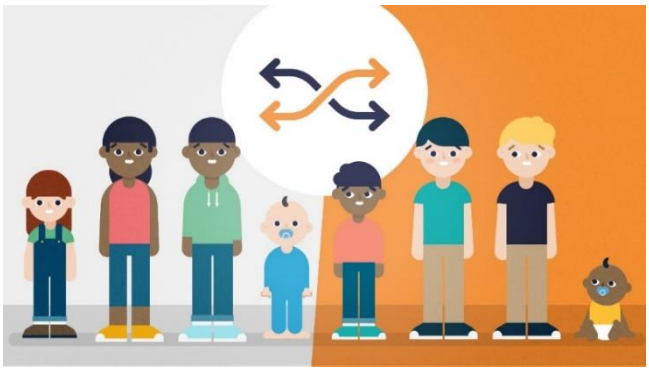
We will explain the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a Consent Form.

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

What is the study treatment?

PRESSURE is a randomised controlled trial, which means that each child is randomly put into one of two treatment groups:

- One group of children receive the intervention, which means they are treated with a lower blood pressure target
- The other group of children are treated with the usual care that they would receive outside of the study



Your child's progress has been closely monitored and they have received all treatments needed to give them the best chance to recover.

What will happen next?

If you agree to continue, you will not be asked to do anything else for the study at this point.

Your child will be treated depending on which group they were in, until they no longer need vasoactive drugs. Your child will continue to be closely monitored. If there are any safety concerns the treating team may adjust the blood pressure target.

So that we can compare the two groups in the study, we will collect information on your child's treatment and progress on the intensive care unit, the duration of their hospital stay and survival to hospital discharge.

Is any follow-up required for the study?

Yes, after twelve 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. If you agree, we will pass your name and contact details onto the Intensive Care National Audit & Research Centre (ICNARC) who will send you the questionnaire and may contact you after a few weeks to find out if you received it.

Do we have to take part?

No, it is up to you and your child (wherever possible) to decide to join the study.

5 What treatment would my child have received if they were not in the study?

If your child had not been a part of the study, they would have received standard treatment in line with the usual care group detailed in Section 4 of this information sheet.

The doctor treating your child would have followed the current guidelines on using vasoactive drugs to treat low blood pressure, but these guidelines are currently based on low quality evidence.

6 What are the possible disadvantages and risks of taking part?

In both groups, patients will receive vasoactive drugs to treat low blood pressure (these are standard treatments used in PICU). Known potential side-effects of vasoactive drugs include:

- abnormal heart rhythms that are not immediately life-threatening
- decreased kidney function
- insufficient blood flow to the intestines
- insufficient blood flow to the limbs, fingers, or toes

All patients will be monitored closely for side effects of vasoactive drugs, as well as any potential side effects associated with lower blood pressure.

If your child is treated in the intervention group (lower blood pressure target)

If your child is in this group, they will receive treatment to keep their blood pressure at the lower target, based on their age, until they can maintain this target on their own (without needing drug treatment). This lower target is the lower end of the normal blood pressure range for their age.

In theory, targeting a lower blood pressure reduces the amount of vasoactive drugs given. A potential benefit of being in this group is that your child may experience fewer side effects.

However, it is possible that staying with a lower blood pressure target may also present certain risks, similar to those above:

- decreased kidney function
- insufficient blood flow to the intestines or other organs
- insufficient blood flow to the limbs, fingers, or toes

If your child is treated in the usual care group

If your child was assigned to the usual care group, they will be cared for by the hospital's clinical team according to the hospital's current practice.

7 What are the possible benefits of taking part?

We cannot promise that your child will benefit directly from participation in the research. The benefits and risks of using a lower blood pressure target to guide treatment, instead of usual care, are currently unclear. By carrying out this research and answering this question, we may help to improve the future treatment of children in intensive care.

8 How will my child's information be used?

The Intensive Care National Audit and Research Centre (ICNARC), based in the UK, is managing the study and will be responsible for looking after your child's information. Your child's information will be kept safe and all data protection laws will be followed.

For this research study, we will need to collect information which is already recorded by the hospital in your child's medical records. This includes information about their treatment in intensive care, including the vasoactive drugs they received, whether they had breathing support and how long they were in PICU. No one will be able to identify your child from this information (i.e. this is non-identifiable information).

If you agree, we will also collect your child's name, NHS number, date of birth, sex and postcode (i.e. identifiable information). This will be shared between the hospital, ICNARC, the NHS national databases (held by NHS England/Digital Health and Care Wales) and the Paediatric Intensive Care Audit Network (PICANet) and will enable us to monitor your child's well-being (survival and any additional hospital admissions). These organisations routinely collect data from patients across the country and there are strict controls in place to ensure confidentiality.

Once we have finished the study, we will keep some of the information so we can check the results, but all identifiable information will be destroyed.

What are my choices about how my child's information is used?

- If you agree to take part, the hospital research team will continue to collect information from your child's medical records for use in the study.
- If you do not wish to take part, non-identifiable information up to the point of your decision will be kept, and some important information for monitoring safety and outcomes will also be collected. This is to ensure the safety of all children taking part in the study and will not allow your child to be identified.

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

You can find out more about how we use your child's information:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to PRESSURE@icnarc.org
- at www.icnarc.org/research-studies/pressure/for-patients

9 Further Information?

Can my child leave the study at any point after they have joined?

You can stop your child taking part in the whole of the study, or just parts of it, at any time and without giving a reason.

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 PRESSURE@icnarc.org.

What will happen to the results of the PRESSURE study?

The results of the study will appear 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. It will not be possible to identify any child who has taken part in the study in any journals, reports or articles.

Who is organising and funding the study?

The study is funded by the National Institute for Health Research (NIHR). Dr David Inwald is the consultant in paediatric intensive care who is leading the study. Cambridge University Hospitals NHS Foundation Trust are sponsoring the study and have delegated responsibilities for managing the study to ICNARC.

Who has reviewed the PRESSURE study?

All NHS research is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by the 'Cambridge South' Research Ethics Committee.

Future Research

We would like your permission to share non-identifiable information about your child with other approved research projects. We would also like your permission to contact you about any future related research studies. If you agree, your contact details will be kept for up to five years after this study.

What if there is a problem?

Complaints: If you have a concern about any aspect of the PRESSURE study, ask to speak with the Principal Investigator 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) - go to www.nhs.uk to find your local PALS contact details. 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 as a result of the study, but we are obliged to mention this possibility. Cambridge University Hospitals NHS Foundation Trust, as Sponsor, has appropriate insurance in place in the unlikely event that your child suffers any harm as a direct consequence of participation in this study. NHS indemnity operates in respect of the clinical treatment which is provided. To leave the study at any point, you can contact the Principal Investigator using the details in Section 10, or by contacting ICNARC by phone on 020 7269 9277 or email to PRESSURE@icnarc.org.

9 Contacts

For more information about PRESSURE, contact the Principal Investigator or Research Nurse at your hospital:

Principal Investigator	Research Nurse
[Insert name, position] [Contact number]	[Insert name, position] [Contact number]

Or visit the study website: www.icnarc.org/research-studies/PRESSURE

If you are unhappy with any aspect of the study:

If you do not wish to speak to the research staff listed above, please contact the Patient Advisory and Liaison Service (PALS): [Insert PALS contact details here].

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

NHS Cambridge University Hospitals NHS Foundation Trust

icnarc intensive care national audit & research centre