

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

Participant Information Sheet (Parents or Guardians)

Version 2.0, 25 August 2022



The **PRESSURE** Study

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

- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether you wish for your child to be included in the research.
- 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 or contact us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you agree for your child to take part you will be given a copy of this information sheet and asked to sign a Consent Form. You will get a copy of that as well. We may also ask your child to sign an Assent Form with you (if it is appropriate to do so).

Important things you need to know

- Your child came to intensive care in an emergency, so it was important to treat them as quickly as possible.
- Your child required medication to increase their blood pressure. Even though these medications are the standard treatment, the best blood pressure level to aim for is not known.
- We want to find out whether reducing the amount of this medication your child receives, by aiming for a lower blood pressure, is more beneficial than the current treatment in the NHS.
- As this was an emergency, your child 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's information to be included in the PRESSURE study.

- Your child's blood pressure is being continuously monitored to ensure their blood pressure remains in a safe range.

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How to contact us

If you have any questions about this study, please talk to your doctor or nurse:

Name of doctor or nurse
Hospital Department
Hospital
Address
Address
Tel:

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, which is a common condition in children in the intensive care unit.

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.

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 more (“vasoactive drugs”), but these treatments carry risks. Currently to guide these treatments, most doctors aim to achieve a blood pressure in the normal range depending on the child’s age. However, currently there is no clear evidence for the best target to aim for.

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 hope to include 1,900 children from 17 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 in the PICU they had low blood pressure and needed to be treated for it.

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

As this was a medical emergency, we could not delay giving the urgent treatment your child needed 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 do I need to do now?

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 can understand the research, 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 care of you or your child.

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. 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 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 How was it decided which treatment group my child was in?

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

Children are put into groups at random by a computer programme. This means your child had an equal chance of being in either group.

What checks on my child's progress will be made?

Your child's progress has been closely monitored and they have received all treatments needed to give them the best chance to recover. Your child's doctors and nurses will take them off the study if they feel this is in their best interests.

6 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 as detailed in Section 5 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.

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

In both groups, patients receive vasoactive drugs due to their condition. 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, regardless of which treatment they received, 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). 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.

8 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.

9 More information about taking part

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

We will follow the law (Data Protection Act 2018) by making sure your child's information is kept private and secure. We will need to use routinely collected information from your child's medical records for this research project. This will include information that is already usually held by the NHS.

If you consent, the hospital research team will use information about your child's treatment and progress recorded in their medical notes for PRESSURE. This information will be anonymised and will be securely sent to ICNARC who are managing the study and will analyse the results at the end of the study. If your child is transferred to another hospital whilst taking part in the study, the hospital research team will contact the relevant team at that hospital to obtain information needed for the study.

If you do not consent, a minimised anonymised dataset will be collected and retained for monitoring safety and important outcomes.

With your permission, we would also like to collect additional information including your child's name, date of birth, postcode and NHS number (see details below under 'will my child's information be sent anywhere else for the study?'). We will also collect your contact details if you are happy to be sent the questionnaire.

Only authorised people will use this additional information to do the research or to check your child's records to make sure that the research is being done properly. People who do not need to know who you or your child are, will not be able to see names or contact details. Any reference to your child's data will use a code number instead.

ICNARC will keep the identifiable information for no longer than one year after the study has finished (unless you have agreed otherwise) and the rest of the

research data will be kept for up to 10 years.

We need to manage your child's records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about your child. You can stop your child being part of the study at any time, without giving a reason, but we will keep information about your child that we already have and ensure a minimised anonymised dataset is collected and retained for monitoring safety and important outcomes. To safeguard your child's rights, we will use the minimum personally identifiable information possible.

Will my child's information be sent anywhere else for the study?

We will ask if we can send identifiable information about your child to ICNARC, so that they can request some important health information (e.g. survival) from the national database of patient records. ICNARC will then securely send information about your child to NHS Digital (who maintain this database) to identify your child using:

- their name
- date of birth
- postcode
- NHS number

NHS Digital will then securely send the survival information back to ICNARC. All information will be stored securely and accessed only by authorised people. Information from these databases is used to support many research studies and there are strict controls in place to ensure confidentiality.

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 [\[link to ICNARC website\]](#)

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.

All the options listed in this section are voluntary and you can change your mind at any time. We will ask you to sign a Consent Form to agree to them.

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 person 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) Health Technology Assessment Programme. 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.

The research team are qualified to do this study as they have all the specialties and

skills needed, including caring for patients and doing health research. Parents of children who have experienced intensive care have been involved in developing the study, including this information sheet and how you were asked to take part.

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 [insert here].

Future Research

Information collected for research can address wider questions beyond those planned in the original study. This has the potential to provide real benefit to patients, the NHS and the scientific community. We would like your permission to share anonymised information about your child with other approved researchers if we feel it could help with 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.

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.

What if there is a problem?

Complaints: If you have a concern about any aspect of PRESSURE, 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 as a result of the study, but we are obliged to mention this possibility.

If you wish to complain about any aspect of the way you have been approached or your child has been treated during this study, contact the hospital's PALS for further information. The NHS Clinical Negligence Scheme for Trusts provides full financial liability for harm caused to participants in the study caused through negligence. Cambridge University Hospitals NHS Foundation Trust provides insurance cover for negligent harm caused as a result of the design and management of the study. In the unlikely event of a claim for which negligence could not be demonstrated, you may need to take legal action for which you would need to pay.

To leave the study at any point, you can contact the Principal Investigator (the person leading the study at this hospital) using the details in Section 10, or by contacting ICNARC by phone on 020 7269 9277 or email to PRESSURE@icnarc.org.

10 Contacts for further information

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

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

and visit the PRESSURE website:

<https://www.icnarc.org/Our-Research/Studies/Current-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.
