

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

> Dr Ravishankar Nagaraj, Dr Adam Nicholls or the PCC Research Team On 0161 701 8056

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: 21/EE/0084 IRAS Number: 289545





This unit is participating in the

# **PRESSURE Study**

A research study about treating low blood pressure in the paediatric intensive care unit



Cambridge University NHS Hospitals NHS Foundation Trust

## What is the purpose of the study?

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

There are many treatments used in intensive care to treat low blood pressure. These include drugs which make blood vessels narrow and make the heart pump more 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, there is no clear evidence currently for what the best target to aim for is.

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

## What will happen?

Treatment for low blood pressure will usually mean a child in intensive care is being treated in an emergency situation. 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 one of two groups by a computer. One group of children will be given a lower blood pressure target. The other group of children will receive the usual treatment they would have been given if they were not involved in the study.

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?

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?

If your child is eligible, joining the study is entirely voluntary. You are free to leave the study at any time.

#### 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.