York and Scarborough Teaching Hospitals NHS Foundation Trust

AUTOFLOW

Data collection to develop ways to predict brain and kidney blood flow

Participant Information Sheet

Part 1

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. A member of the research team will go through this information sheet with you and answer any questions you have. This should take about 10 minutes. Please talk to others about the study if you wish.

Part 1 of the information sheet tells you the purpose of the study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

The brain has a high and constant requirement for oxygen to be delivered by the blood to its cells, and it is the blood pressure that provides blood flow to the brain. In order to keep this supply constant there is a process called autoregulation. What this means is that, over a wide range of blood pressures, the blood flow to the brain remains constant so that it gets all the oxygen that is required. However there are limits to this protective mechanism, and above and below certain limits this process no longer works, and blood flow to the brain is directly related to the blood pressure. What these limits are vary from person to person.

We can measure how much oxygen the brain has by using something called near infrared spectroscopy that shines a certain type of light into the brain tissue. This is done by simply placing two sticky sensors on the forehead and it is painless and safe. By looking at the blood pressure measured in different ways, and the amount of oxygen in the brain, we hope that we can develop algorithms that can predict when brain oxygen levels are likely to drop in the future. If we can do this it would allow clinicians prior warning of the likelihood of low brain oxygen so that they can potentially treat and avoid this, as lower levels have been linked to complications after surgery.

Why have I been invited to take part in this study?

We are inviting you to take part in this study because you are having surgery in York Hospital, and that surgery will take around two hours or more. Also as part of your normal care you will be having a drip placed in your wrist that will look at your blood pressure whilst

you are asleep. This is part of your normal care as decided by the doctors looking after you and has nothing to do with this research.

Do I have to take part?

It is up to you to decide whether to join the study, we will describe 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. You are free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive.

What will happen to me if I take part?

Before you go off to sleep for your operation we will place two sticky sensors on your forehead to measure your brain oxygen saturations, and another two sticky sensors will be placed on your thigh and on your side to look at oxygenation in different tissues. We will also place a small cuff on your finger to measure your blood pressure in a way that is different from the drip in your arm. This cuff will go tight on your finger but is not uncomfortable. We will simply collect all these measurements so that we can analyse them later, but we will not be using them to treat you. The care you receive will be the same as if you didn't take part. The data collected will be sent to a medical device company in the United States called Edwards Lifesciences to analyse, but it will not contain any information that could identify you. Once your operation is over and you have woken up your role in the study is over. You will not have to come back to hospital as part of the study.

If you decide to take part in the study, we will also collect some information from you, or from your notes, about your age, gender, general health, and what medication you are taking. Your decision whether or not to take part in the study will not affect how we give your anaesthetic or how the surgeon does your operation.

Expenses and payment

There are no expenses or payments made for being part of this study

What are the possible disadvantages and risks of taking part?

As with all optical sensors there is a small but theoretical risk of minor heat burn to your skin from the infra-red light source used. The design of the device includes safeguards, and this risk is believed to be minimal. Overall risk is estimated to be low for the sensors and site checks are performed on a regular basis. The finger cuffs could theoretically cause pressure damage to your skin if placed too tightly, however no reported cases have been described.

What are the possible benefits of taking part?

There are no individual benefits in taking part but the information we collect from this study may help other patients in the future.

What if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. Detailed information on this is given in Part 2.

Will my taking part in this study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details of how we will do this are given in Part 2 of this information sheet.

If the information in Part 1 of this sheet has interested you and you are considering taking part, please read the additional information in Part 2, before making any decision.

Part 2

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive. If you decide to withdraw from the study we will use the information we have collected from you up to the point of your withdrawal.

What if there is a problem?

If you are unhappy with the treatment or service you have received from York Hospital you are entitled to make a complaint, have it considered, and receive a response. You can do this verbally by contacting the Patient Experience Team at the hospital by writing to them at

Patient Experience Liaison Office (PALS)
York Teaching Hospital NHS Foundation Trust
York YO31 8HE

by phoning them on (01904) 726262 or by emailing them at:
patientexperienceteam@york.nhs.uk

If you remain unhappy and wish to complain formally, you can do this by contacting the Parliamentary and Health Service Ombudsman, who is independent of the NHS and government, at 0345 015 4033. You may also find help online at:
http://www.nhs.uk/choiceintheNHS/Rightsandpledges/complaints/Pages/AboutNHScomplaints.aspx

Will my taking part in the study be kept confidential?

Information we collect from you as part of the study will be recorded on paper and/or on a computer database. The research team at the hospital will each have unique passwords to access the database. You will be given a numeric code, unique to this study, and this code will be used on the case record file and the database rather than your name, so you cannot be immediately recognised from the information.

The code linking your name with the information we collect during the study will be kept in separate locations so that you cannot be easily identified.

If you join the study some parts of your medical records and the data collected for the study will be looked at by one or two authorised people from the Research and Development Unit at the hospital. This is because the R&D Unit has a duty to check that the research is being carried out correctly. All these people will have a duty of confidentiality to you as a research participant.

What will happen to the results of the research study?

The results of the study will be used to help us develop algorithms to predict the likelihood of low oxygen levels in the brain occurring in the future. We intend to publish the results of the study in reports and specialised medical journals read by anaesthetists

and surgeons. The results of the study will only be described as a summary of the whole group experience and not of individuals.

Who is organising and funding the research?

The study has been designed and will be run by Dr Simon Davies and Consultant Anaesthetists at York Hospital, as well as Professor Thomas Scheeren and his colleagues at Groningen Hospital in the Netherlands.

This study is being funded by a company called Edwards Lifesciences, but they have no say in how the study is run. The study is being sponsored by the hospital. This means that York Hospital is takes overall responsibility for the way the research has been designed and is conducted.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This is to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland.

The study has also been reviewed by the Research and Development Unit at York Hospital.

Further information and contact details

If you would like further information about the study, please contact:

Dr Simon Davies
Department of Anaesthetics
York Hospital, York United Kingdom
Tel: 01904 725399

If you would like general information and advice about taking part in a research project, please contact:

Dr Deborah Phillips (Research Advisor, Research and Development Unit)
Deborah.phillips@york.nhs.uk
01904 726954

If you are unhappy about any aspect of this study or wish to make a complaint, please contact Dr Simon Davies, Dr Deborah Phillips or The Patient Experience Liaison Office (PALS) using the contact details provided.