INSERT HOSPITAL LOGO

TIGHT K

The impact of potassium levels on post-surgical heart rhythm

Patient Information Sheet

We would like to invite you to consider becoming involved in a research project. This information sheet provides information about the research and explains how you will be involved if you agree to take part.

Trial sponsor: Barts Health NHS Trust

Tight K Trial
A randomised clinical trial

Why have I been approached?
You are being approached about this study because you are about to undergo coronary artery bypass graft (CABG) surgery. After your surgery, your health will be carefully monitored in the intensive care unit or surgery step-down ward. We would like invite you to take part in a study that is looking into one aspect of your care following surgery.

Before you decide whether to participate in this research, we would like to tell you about why it is being done and what it will involve. Please take time to read the information carefully and you may wish to discuss with members of your family and your friends.

Why are we doing this research?
Following CABG surgery, an irregular heart rhythm (arrhythmia) called atrial fibrillation after cardiac surgery (AFACS for short) can occur in around one third of patients. People who develop AFACS are more likely to develop other medical problems and spend longer in hospital. To try to lower the chance of AFACS occurring, some doctors give potassium to patients for a few days after CABG surgery.

Potassium, also known by its chemical name K, is an important mineral in the blood. It is vital for normal heart function. The level of potassium in the blood is measured in milliequivalents per litre, which is shortened to mEq/L.

Many doctors believe that AFACS can be prevented by maintaining high levels of potassium in your blood after surgery. However, there is currently no evidence to support this. Recent research has suggested that maintaining potassium at a lower level within your blood may work just as well.

In other words, there is uncertainty about the benefits of giving extra potassium. To resolve the uncertainty, we need to do a research study.

We want to find out if maintaining your normal level of potassium in your blood can help to prevent AFACS just as well as maintaining a high level of potassium.

Do I have to take part?
No. It is up to you to decide whether or not to take part. Your participation is entirely voluntary. Please take as much time as you need to consider whether you would like to participate. We welcome any questions you may have.

If you agree to take part but at a later date you change your mind, you are free to withdraw from the research at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you would like to withdraw, please contact the study co-ordinator using the details at the end of the leaflet.

What will happen to me if I take part?

You will have the opportunity to discuss the study with your doctor or nurse, and to talk about any questions you have. If you are happy to take part, they will ask you to sign a consent form for the study at the clinic. You will be given a copy of the consent form and this information sheet to take home with you. You will also be asked to complete a short questionnaire about your quality of life. There will be no difference in your normal standard care leading up to, during or after your CABG surgery.

Following CABG surgery, all patients spend some time on the intensive care unit or surgery step-down ward as part of their normal recovery period. During this time, we will either keep your potassium at a normal level (known as **relaxed control**) or a high level (known as **tight control**). Small samples of blood are routinely taken to check the levels of potassium in your blood as part of your normal hospital care.

We will also monitor the rhythm of your heart for 5 days (or until you are discharged) following your surgery. We will apply a wearable device to your chest that is very similar to having an ECG (electrocardiogram). This device is called a Holter monitor. The device will be portable so you can carry on with your normal activities. It is about the size of a ten pence coin (see pg. 9 for a picture of the monitor). The device will not stop you from getting out of bed or taking a shower. This device will give us additional information about your heart rhythm during your stay in hospital. Once the 5 days are complete, the heart rhythm information will be analysed by researchers at Wythenshawe Hospital in Manchester. They will be looking for episodes of irregular heart rhythm. Your doctor will let you know if the researchers in Wythenshawe Hospital notice any problems with your heart rhythm. Your doctor will then decide if you need further treatment.

When you are discharged from hospital, you will be seen in the outpatients department as part of your normal standard care following CABG surgery.

A nurse will also contact you by telephone, email or post six months after your CABG surgery to see how you are. The nurse will also ask you to complete another short questionnaire about your quality of life since you left hospital.

To complement the data we collect about your health during this study, we would like to access your health records held with NHS England and other central UK government bodies that hold health data for linkage. We will access data covering a period of 6 months following your CABG surgery.

We will look at this information, along with the information we specifically collect for the trial, as this may help us better understand why one person gets an abnormal heart rhythm after surgery and another does not.

How will my treatment be decided?

This will be decided by chance (randomisation) using a computer. This is essential to ensure that the results of the study are valid and is a routine step in many studies. You have a 50% chance of receiving one or other treatment.

What is the difference between the two treatments?

The group of patients who are in the **relaxed control** arm will receive potassium (either by tablet or directly into a vein, through a 'drip') when the measurement of potassium in the blood falls below the lower limit of the normal range for potassium (3.6 mEq/L).

The group of patients who are in the **tight control** arm will receive potassium (either by tablet or directly into the vein, through a 'drip') when the measurement of potassium in the blood falls below the lower limit of the higher range for potassium (4.5 mEq/L).

Will I know which treatment I will receive?

Yes, you will know if you are in the **relaxed control** group or the **tight control** group. The nurses and doctors looking after you will also be aware of which group you are in. It will also be recorded in your hospital notes.

Will extra blood samples be collected?

There will be no extra blood samples collected as part of the Tight K study. Bloods that are taken are all part of normal care following CABG surgery.

Are there any risks of taking part in the study?

There is a small risk that you may experience some skin irritation from the Holter monitor stickers.

There is a chance you will experience an irregular heart rhythm. If you are in the relaxed control group and experience an irregular heart rhythm you will then be treated according to usual clinical care (tight control).

Potassium supplements are part of normal standard care for patients after their CABG surgery. They may carry some risks for patients. For example, potassium given as a tablet can have an unpleasant taste and may cause gastrointestinal upset, such as constipation.

All other treatments will be given according to standard clinical care. You will be closely monitored as all patients would be in hospital.

What are the potential benefits?

There may not be any direct benefits to taking part. The information we get may help improve the treatment of people who are undergoing heart surgery in the future and the wider NHS.

Will my taking part be kept confidential?

Please see the section "What will happen to my data" for further information on how we will keep your participation and data collected confidential.

Will anyone else be informed of my involvement in this study?

Yes, when we ask you to consent to participate in the study, we will ask for your permission to send a letter to your GP informing them of your involvement.

Who has reviewed the Study?

This study was reviewed and approved by *Queen Square* Research Ethics Committee on 6th November 2019. The REC reference number is 19/LO/1064.

Who is organising and funding the research?

The study is being run by the Clinical Trials Unit at the London School of Hygiene & Tropical Medicine. The study is funded by the British Heart Foundation. The sponsor of the study is Barts Health NHS Trust.

What will happen to my data?

The study is being run by the Clinical Trials Unit at the London School of Hygiene & Tropical Medicine. They are responsible for collecting and looking at the data. *INSERT HOSPITAL/TRUST NAME* will collect information from you and your medical records for this research study in accordance with our instructions.

To protect your confidentiality, you will be allocated a study number which will be used instead of your name or date of birth to identify you on all subsequent forms.

INSERT HOSPITAL/TRUST NAME will use your name, date of birth, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Barts Health NHS Trust, the London School of Hygiene & Tropical Medicine and regulatory organisations may look at your medical and research records to check the accuracy of the research study. *INSERT HOSPITAL/TRUST NAME* will only pass on your NHS number and date of birth to Barts Health NHS Trust and the London School of Hygiene & Tropical Medicine, along with the information collected from you and your medical records. No other identifiable information will be shared with these organisations. Wythenshawe Hospital will not receive any identifiable information.

Along with the data we collect about your health during this study, we would like to access your health records held with NHS England, and other central UK government bodies that hold health data for linkage, so that we can assess your health outcomes.

Members of the team at Barts Health NHS Trust and the London School of Hygiene & Tropical Medicine will send your unique participant ID, your NHS Number or Community Health Index and your date of birth to NHS England and other central UK government bodies that holds data for linkage. This will allow us to collect health data about you relevant to the study including hospital admissions using Hospital Episode Statistics data. We will ask for your permission to do this on the consent form.

This anonymised data will also help us to identify the factors that predict AFACS, and help us better manage this condition in the future.

The data that are sent back to the London School of Hygiene & Tropical Medicine for analysis will be identified by a participant ID, and will not include any information that identifies you personally. This is called pseudonymisation. The information will be imported into a secure database managed by the London School of Hygiene & Tropical Medicine.

INSERT HOSPITAL/TRUST NAME will keep identifiable information about you from this study for 15 years after the study has finished.

Barts Health NHS Trust will act as the data controller for this study. This means that they are responsible for looking after your information and using it properly.

The London School of Hygiene & Tropical Medicine will keep your trial data, including your NHS number/CHI Index, for 15 years after the study has finished. The information will be stored in a secure archiving facility.

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 your rights, we will use the minimum personally-identifiable information possible. To withdraw all the data collected on you from the study, please speak with the research team.

You can find out more about how we use your information at https://bartshealth.nhs.uk/privacy

Future research
When you agree to take part in a research study, all the information we collect about your health and care for this research study may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or commercial organisations involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-

policy-framework-health-social-care-research/).

We will ask for your permission to share non-identifiable (anonymised data) information with other researchers on the consent form. This information will not identify you and will not be combined with other information in a way that could identify you. This means it is anonymised data. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make automated decisions about future services available to you, such as insurance or marketing.

What will happen to the results of the research study?

The results will be published in a reputable medical journal. No data that could identify you will be used in any reports or publications. The local research nurse or doctor will let you know the results of this study once they are published.

What if relevant new information becomes available?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor/nurse will tell you about it and discuss whether you want to continue in the study.

What if there is a problem?

If you have any concerns about any aspects of this study, you should ask to speak to the researcher who will do their best to answer any questions (contact details on the last page of this information sheet).

We would not expect you to suffer any harm or injury because of your participation in this study. If you are harmed by taking part in this study, compensation will be in accordance with the guidelines of the Association for British Healthcare Industries (ABHI) and copies of these guidelines are available on request.

If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you. Please contact Patient Advisory Liaison service (PALS) if you have concerns regarding the care you have received, or as an initial point of contact if you have a complaint. You are welcome to ask the researchers if you would like more information on this.

Details of how to contact the researchers

Investigator's name: *ADD LOCAL DETAILS*
Phone number: *ADD LOCAL DETAILS*

Study Coordinator's name: *ADD LOCAL DETAILS*
Phone number: *ADD LOCAL DETAILS*

Complaints Department / Patient Advice and Liaison services (PALS) *(delete as appropriate)* telephone number: *ADD LOCAL DETAILS*
NHS Trust responsible for your care: *ADD LOCAL DETAILS*

Chief Investigator details

Professor Ben O'Brien
Consultant in Intensive Care Medicine and Cardiac Anaesthesia
Barts Health NHS Trust
St Bartholomew's Hospital
West Smithfield
London
EC1A 7BE
Study website: https://www.lshtm.ac.uk/research/centres-projects-groups/tight-k

Picture of the Holter monitor as described on pg. 3.