

**Phase III mechanistic, randomised controlled trial of Stopping Perioperative Angiotensin II Converting Enzyme inhibitors and/or receptor blockers in major noncardiac surgery**

**PATIENT INFORMATION SHEET**

**Version 2.0 (dated: 24.11.2016)**

**PI: [Insert PI name]**

**IRAS ID: 207629**

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**Introduction**

We are inviting you to take part in a clinical trial, which we hope will improve the care of patients who have surgery. Before you decide, it is important to understand why we are doing this research and what it involves. Please take time to read the following information and decide whether or not you wish to take part. Talk to your friends and family about the trial if you wish. Ask us if anything is unclear.

**Why are we doing this research?**

We are studying better ways to look after patients who have surgery. We hope these new techniques will help patients recover more quickly after surgery, so they can return home sooner, and in better health. One approach that may help is to continue to use a commonly prescribed medications called Angiotensin Converting Enzyme (ACE)-nhibitors and Angiotensin Receptor Blockers (ARB), which may help limit the amount of stress to the heart that occurs in about 1 in 3 patients following major surgery. Although this treatment shows promise, we need to confirm these findings. This trial will tell us if we should be using this treatment in every patient who may benefit.

**Why have I been invited?**

We have invited you because your surgeon has recommended you for an operation where this treatment may have particular benefit.

**Do I have to take part?**

No. It is up to you to decide whether or not to take part in the trial. If you decide to take part, we will ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. If you decide not to take part, or later to withdraw, this will not affect the standard of care you receive.

**What will happen to me if I take part?**

Your operation will proceed as planned, and almost all of your treatment will not change. Before your surgery, you will either be offered to stop your regular ACE-inhibitor and/or ARB drug (which is the standard treatment in around half of hospitals) or you will continue these drugs throughout the time after surgery. The choice of treatment is made at random, so neither you nor your doctors will be able to choose which you receive. You will receive a patient advice letter confirming your trial allocation to stopping or continuing their ACE-I and/or ARB. Additionally you will reminded by telephone call and text message, or in person if they are in hospital. If you are not in hospital, you will receive another telephone call and text message, the day before surgery.

We will obtain a blood sample (usually at the same time as your routinely required blood samples, whenever possible) and also as a part of standard care measure your heart rate and blood pressure just before surgery and after surgery. The blood samples obtained during the course of this study will be stored and analysed only for the purposes of this trial to see how stopping/continuing these drugs alters blood pressure/heart rate and blood cell function and will be destroyed after completion of the study If you are randomized to stop these drugs, these will be restarted around 24-48 hours after you wake up from your operation. These drugs will be continued or restarted by your doctor as long as there are no signs that this may affect your blood pressure or kidney function (as is normal practice for prescribing them). If you are allocated to receive the usual treatment then none of your medical care will change. If your blood pressure becomes high after surgery, this will be treated either with your regular ACE-inhibitor or ARB drug, or an alternative drug, based on clinical review by the surgical team looking after you after surgery. On the first two days after surgery, we will obtain a blood sample (usually at the same time as your routinely required blood samples, whenever possible) to check whether your heart shows signs of stress. We will measure your heart rate and blood pressure for 2 days after surgery to see how stopping/continuing these drugs alters blood pressure/heart rate. After the first two days, we will come to see you to follow your recovery, reviewing your medical notes until you leave hospital.

**What are the possible risks and benefits of taking part?**

The risks of this trial to your health are very small. Many surgeons/anaesthetists instruct patients to stop these drugs, while many advise to continue them. This reflects the uncertainty as to what doctors should actually do. Early studies suggest that continuing these drugs may benefit many patients in this trial. There is a very small risk of high or low blood pressure for some patients. For this reason, you will be closely monitored throughout the study period and, if necessary, the research team will make adjustments to your treatment to make sure you are as safe.

**What will happen if I don’t want to carry on with the trial?**

You can request to stop taking part in the trial at any time, but we would still like to follow your recovery because this will still provide important information about how well your treatment worked. If you prefer, you can request that you no longer take any part in the trial and we will not contact you or review your medical notes any further.

**What if I am not happy about the trial?**

We will only make small changes to the way you are cared for in hospital. It is unlikely that these small changes would cause any problems. However, if you have a concern about any aspect of this trial, you should ask to speak with someone from the research team, who will do their best to answer your questions. You may also contact the doctors and nurses who lead the trial at this hospital on the telephone number at the bottom of this information sheet. You may also contact your Patient Advisory Liaison Service (PALS) [change according to site-specific department name] if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone [insert site specific telephone number] or email [insert site specific email]. You can also visit PALS [change according to site-specific department name as above] by asking at hospital reception.

**Indemnity**

Queen Mary University of London has agreed that if you are harmed as a result of your participation in the trial, you will be compensated, provided that, on the balance of probabilities, an injury was caused as a direct result of the intervention or procedures you received during the course of the trial. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the trial. These arrangements do not affect your right to pursue a claim through legal action.

**Confidentiality**

The information we collect about you will remain strictly confidential and nothing that might identify you will be revealed to any third party. Your medical notes will be seen by authorised members of the research team at your hospital so that they can collect information needed for this trial. Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Act 1998. Information from national databases will be obtained via strictly confidential communication. We are required by research regulations to keep the trial data for a minimum of 20 years after the trial has been completed. Occasionally, some patients lose touch with their hospital following their surgery and we will need to collect important basic information from national records. To ensure we identify you correctly, we will need to provide your name, date of birth, postcode and NHS number to the government agencies that keep these records. All data will be securely transferred and stored safely on NHS computers in line with strict regulations.

**Who is organising and funding the research?**

The trial is funded by the Royal College of Anaesthetists British Oxygen Company Research Chair in Anaesthesia. The trial is sponsored by Queen Mary University of London and run by the Critical Care and Perioperative Medicine Research Group at Queen Mary University of London. Your doctor will not receive any payment for including you in the trial.

**Who has reviewed the trial?**

All research in the NHS is reviewed by an independent Research Ethics Committee, to protect the interests of the patients who take part. This trial has been reviewed and granted a favourable opinion by the London - Central Research Ethics Committee and has also been approved by NHS Research and Development.

**Thank You**

Thank you for considering taking part in this trial and for reading this information sheet, which is yours to keep. If you decide to take part in the trial, you will also be given a copy of your signed consent form.

Your trial doctor is:

Name: Contact phone number:

Your research/specialist nurse is:

Name: Contact phone number: