

**Optimisation of Peri-operative Cardiovascular Management to Improve Surgical Outcome II (OPTIMISE II) Trial**

**PATIENT INFORMATION SHEET (UK)**

**Version 4.1 16/07/2018**

**PI: [Insert PI name]**

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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 new ways of looking after patients who have surgery to help them recover to return home sooner, and in better health. Previous research has shown that a treatment used during surgery and shortly afterwards, may improve the amount of oxygen delivered to thebody’stissues and reduce the number of patients who develop an infection after surgery. This treatment involves using a heart monitor (called a cardiac output monitor), intra-venous fluids (given into a vein) and drugs which improve heart function. Although this treatment shows promise, we need to confirm the findings of small studies in a much larger clinical trial taking place in many hospitals around the world. This will tell us if we should be using this treatment in all every patient who may benefit.

**Why have I been invited?**

We have invited you because you are going to have a type of surgery 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?**

During and after your operation, an experienced doctor or nurse from our research team will help look after you, take some extra measurements and make sure the study treatment is correctly administered. Your surgery will proceed as planned, and almost all of your treatment will not change. During and after your surgery, you will receive one of two study treatments, either the trial treatment or standard care. This decision will be made at random and neither you nor your doctor will be able to decide which study treatment you receive. Although your doctor will be aware of which treatment you will receive, you will not be told. Your experience will be the same regardless of which treatment you receive, and you probably won’t be able to tell which one you are getting. Both treatments will begin at the start of your surgery and finish four hours after this has ended. The two treatments involve slightly different ways of deciding the amount of intra-venous fluid and drugs to improve your heart function that you will receive. If you receive standard care your doctor will use measurements such as heart rate and blood pressure to guide these treatments. If you receive the new trial treatment we will also measure the amount of blood your heart pumps each minute using an extra monitor. These extra measurements should help your doctor to decide how much intra-venous fluid and drugs to improve your heart function they will give.

After the treatment is over we will review your medical records and may talk to your doctors to collect information about you and your recovery. We will also contact you by telephone in one month and again in six months’ time to ask you some simple questions about your wellbeing. This phone call will last around five minutes and will provide useful information about your recovery. With your permission, we may also contact your General Practitioner (GP) prior to contacting you, or if we are not able to reach you directly.

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

Previous research suggests that the treatment we are investigating is very safe and should benefit most patients. However we would like to collect additional safety information, and you will be closely monitored throughout the study period to ensure the treatment is safe.

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

You can opt out of the trial at any time before or after surgery, but we would still like to follow your recovery because this will 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. In this case we would like to keep the information we collected about you up to the point of leaving the trial unless you specifically request that we do not do this.

**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. 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**

Queen Mary University of London is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen Mary University of London will keep identifiable information about you for 20 years after the study has finished. 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. You can find out more about how we use your information at <http://www.jrmo.org.uk/>.

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. De-identified data will also be shared with other authenticated researchers for further research and research publications on this topic, but only if they guarantee to preserve the confidentiality of the information requested. 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. 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 NHS agencies that keep these records. All data will be securely transferred and stored safely on NHS and Queen Mary University computers in line with strict regulations.

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

The trial is funded by Edwards Lifesciences and National Institute for Health Research (part of the NHS). Edwards Lifesciences, a company that has specialised in the manufacturing of cardiac output monitoring equipment for many years, will be supplying all the devices to the participating sites involved in the study. 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 NN –NN Ethics Committee and has also been approved by the NHS Health Research Authority.

**What will happen to the results of this study?**

We hope to publish the results in a scientific journal. It will not be possible to identify any individual who has taken part from this scientific report. Copies of the report will be available on request, and we will also provide a summary of the results in non-medical language on our trial website [www.optimiseii.org](http://www.optimiseii.org).

**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: