



## **A clinical trial of blood flow optimisation for patients who have emergency bowel surgery**

### **PATIENT INFORMATION SHEET**

**(For use in England and Wales only)**

**Version 6.0 01/07/2020**

**PI: [Insert PI name]**

**IRAS number: 214459**

#### **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 more quickly, 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 the body's tissues and reduce the number of patients who develop complications after surgery. This treatment involves using a heart monitor (cardiac output monitor) to help your clinical team decide the amount of intra-venous fluid (given into a vein) you will receive. There is some evidence from smaller studies that this treatment is beneficial, however we need to confirm this in a much larger clinical trial. We are running this trial in 100 hospitals in the UK that are taking part in a national project aiming to improve care for patients going through this surgery (the National Emergency Laparotomy Audit, NELA). Because NELA already collects a lot of information about patients going through this surgery and will share this information with us (with your permission) we can carry out this research without asking you a lot of extra questions. The trial results 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 you are going to have a type of surgery where this treatment may have particular benefit.

### **Do I have to take part and what if I change my mind?**

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 or your legal rights.

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

***Please see the flowchart at the end of this information sheet.*** Your surgery will proceed as planned, and almost all of your treatment will be the same. During and after your surgery, you will receive one of two study treatments, either the trial treatment or usual care. This decision will be made at random and neither you nor your clinical team will be able to decide which study treatment you receive. Although your clinical team 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 six hours after it has ended. The two treatments involve slightly different ways of deciding the amount of intra-venous fluid you will receive. If you receive usual 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 will help your doctor to decide how much intra-venous fluid they will give.

After the treatment is over your care will continue as normal. *We do not need to contact you further.* We will use routinely collected information to follow up your recovery after surgery (see below).

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

Previous research suggests that the treatment we are investigating is safe and should benefit most patients. You will be closely monitored throughout the study period and, if necessary, your clinical team will make adjustments to your treatment to make sure you are safe.

### **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. University Hospital Southampton NHS Foundation Trust 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.

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

The trial is funded by the National Institute for Health Research (part of the NHS). It is sponsored by University Hospital Southampton NHS Foundation Trust (UHS) and run by the Critical Care and Anaesthesia Research Unit at UHS and the Pragmatic Clinical Trials Unit at Queen Mary University of London (QMUL). Your doctor will not receive any payment for including you in the trial.

### **How will we use information about you?**

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Regulations. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. Nearly all the information that we need to look at for this trial is already collected by NHS and government organisations *as a routine part of your care*. These organisations hold confidential information so the way they handle information is tightly regulated and their databases will keep all information about you safe and secure. The organisations are:

- The Royal College of Anaesthetists; collects information about the care you receive while you are in hospital for this surgery for the National Emergency Laparotomy Audit (NELA); “the audit”.
- NHS Digital (or equivalent organisations in Wales and Scotland\*); holds information on hospital admissions (Hospital Episode Statistics) and mortality data sourced from Civil Registration Data and supplied by NHS Digital on behalf of the Office for National Statistics (ONS).

Nothing that might identify you will be revealed to parties other than the trial team at UHS, QMUL, Sealed Envelope (the randomisation system provided by QMUL) and the organisations above. We will need to use information from your medical records for this research project. If you take part in this trial, authorised members of the research team will look at your hospital medical notes alongside your clinical team to enter information into the secure online NELA database. This will include a small amount of additional information about the treatment we gave you as part of the trial. The research team will also record some *identifying information* about you (NHS number, date of birth, gender and postcode) on a secure system provided by our Trials Unit at QMUL. People will use this information to do the research or to check your records to make sure that the research is being done properly. Getting information from the organisations above means we do not need to contact you to do this.

When the trial has finished, the Trials Unit at QMUL will request information about everyone who took part from both NELA and NHS Digital (or equivalent in Wales and Scotland\*). This is so that we can see whether the trial treatment was effective overall. To do this:

1. NELA will share data with us about your hospital care, for example the details of your surgery, how long you spent in hospital and the treatment you received as part of the trial. They do **not** need to send us personal information about you. Instead they will use a unique identification (ID) number that you will be given when you agree to take part in the trial.
2. Meanwhile the Trials Unit will send your identifying information as listed above to NHS Digital so that they can check your records and let us know your health status 90 days and one year after you were treated in the trial. The identifying information we send is the minimum amount we can use to make sure we get information about the right person. It is transferred securely to maintain confidentiality, and the information NHS

Digital sends back uses your unique trial ID number but not your identifying information.

3. Information received from NELA and NHS Digital is combined at the Trials Unit, and any information that could identify you is removed. The unique ID number will be used to make sure the records from NELA and NHS Digital match each individual correctly. It will not be possible to identify individual trial participants when the results are released.

During the trial, authorised staff from the sponsor (University Hospital Southampton) or its representative (the Trials Unit at QMUL) may need to review your medical notes and NELA record in order to check that the trial is being carried out in line with approved procedures at your hospital. During this trial monitoring no further identifiable information about you will be recorded or removed from your hospital.

In the future, anonymised data (i.e. data which would not identify you) will be shared with other researchers for further studies and publications on this topic, but only if they guarantee to preserve the confidentiality of the information requested. The Trials Unit has procedures in place to review any future requests for data. Once we have finished the study, we will keep some of the data (we are required by research regulations to keep the trial data for a minimum of 20 years after the trial has been completed) so we can check the results.. All data will be securely transferred and stored safely on NHS and QMUL computers in line with strict regulations. We will keep all information about you safe and secure.

\*For patients in Wales, information will come from the ONS and the Patient Episode Database for Wales. In Scotland it will come from the NHS National Services Scotland Information Services Division.

### **What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from NHS Digital. If you do not want this to happen, tell us and we will stop. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. Please contact the trial doctors or nurses on the telephone number below, or ask your clinical team to contact them on your behalf if you are considering opting out of the trial. Withdrawing from the trial will not affect your medical care or legal rights.

Data collected by your clinical team for NELA is used to improve care for patients undergoing this surgery. More information about the NELA project is available at <http://nela.org.uk/PatientInformation>. If you do not want to take part in the FLO-ELA trial and **in addition** do not want your data collected for the wider NELA project, you are free to opt out. In order to do this, please email [info@nela.org.uk](mailto:info@nela.org.uk) and put "Patient request to opt-out" in the subject line. Alternatively, please notify a member of your local care team that you wish to opt out. NELA will then ensure that your details are not entered in the audit. If they have already been entered, NELA will ask for them to be removed.

### **Where can you find out more about how your information is used?**

You can find out more about how we use your information

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- the leaflet available from [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch). Please ask your research nurse if you would like a paper version of this leaflet.
- by emailing our Sponsor's Data Protection Officer at [dataprotection@uhs.nhs.uk](mailto:dataprotection@uhs.nhs.uk)

### **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 – Bromley Research 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. We will write our reports in a way that no-one can work out that you took part in the study. 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.floela.org](http://www.floela.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:

## Summary of the FLO-ELA trial

