Insert Hospital logo

Comparison between Propofol and Inhalational Anaesthetic Agents on Cardiovascular Outcomes following Cardiac Surgery
A Randomised Controlled Feasibility Trial

Patient Information Sheet

We would like to invite you to take part in our research study. This information sheet is designed to explain what will be required if you agree to take part.

COPIA Feasibility Study
A randomised controlled trial

Joining the study is entirely up to you. Before you decide we would like you to understand why the research is being done and what it would involve. Please take time to read the information carefully and discuss with others if you wish.

Part 1

What is COPIA?

COPIA (**Co**mparison between **P**ropofol and **I**nhalational **A**naesthetic Agents on Cardiovascular Outcomes following Cardiac Surgery - a Randomised Controlled Feasibility Trial) is a clinical research study. COPIA will look at the differences in the outcomes of patients receiving two different types of anaesthetics during heart surgery. Both types are currently used in normal practice.

Why have I been approached?

You have been scheduled to undergo a heart operation called Coronary Artery Bypass Graft surgery (CABG).

What is the purpose of the study?

CABG is the best known treatment of choice for selected groups of patients with significant narrowings and blockages of the heart arteries (coronary artery disease). The surgery is carefully managed, but sometimes there is a risk of complications such as heart damage, kidney damage and stroke.

There are two types of anaesthetic usually used in the UK:

- A gas, which is inhaled. This will be either Isoflurane, Sevoflurane or Desflurane. These are known as **volatile anaesthetics**.
- A drug called Propofol, which is given through a drip into a vein. This is known as **propofol anaesthetics**.

We think it may be possible to reduce the risk of complications of CABG by using volatile anaesthetics instead of a propofol anaesthetic during surgery.

Some research has suggested that volatile anaesthetics could reduce complications after heart surgery, when compared to propofol anaesthetics. Volatile anaesthetics have been shown to protect the heart, the kidneys and the brain. However, these findings are from small studies in people and animals. We now want to see if a larger study will support these results.

We want to see if this study will work in NHS hospitals. We are doing a small study (called a feasibility study) in 50 patients in two hospitals in London (King's College Hospital and Guy's & St Thomas' Hospital). If this is successful, we will do a larger study in 2900 patients in hospitals throughout the UK.

Will all patients receive the same anaesthetic?

No, there will be two separate groups. Half of the patients will receive volatile anaesthetics during heart surgery, and half will receive the propofol anaesthetics.

How will this be decided?

The groups will be randomly selected using a computerised system. This is a routine step in many studies and is essential to ensure that the results of the study are scientifically strong and valid. You have a 50% chance of getting one or the other treatment.

When will I find out which type of anaesthetic I was allocated?

You can find out which type of anaesthetic you were allocated after the study has finished. The contact details of the research nurse/team to contact for this information is listed on the last page of this document.

Who else will know what anaesthetic I was allocated?

Staff at the hospital will be arranged into 'blinded' and 'unblinded' teams before they begin recruiting patients into the study.

Blinding (not knowing which treatment a patient has been given) is an important element of most research studies as it helps to reduce the risk of bias when comparing the treatments.

Staff who are 'blinded' are those who will not be made aware of the type of anaesthetic given during your surgery. This will include the research nurse collecting follow up data after the surgery.

Staff who are 'unblinded' are those who will be made aware of the type of anaesthetic given during your surgery. This will include the anaesthetic team (anaesthetist or anaesthetic practitioner), and research nurses who help with collecting information during the surgery.

What if my doctor needs to find out which anaesthetic I was allocated?

Your doctor will have full access to be able to find out what anaesthetic you were given, at any time. The type of anaesthetic you are given during surgery will be kept in a sealed envelope in your medical records until you are discharged, then they will be kept in a secure locked cabinet after discharge.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you agree to take part, you will be asked to sign a consent form. You are free to withdraw without giving a reason.

A decision to withdraw or a decision not to take part will not affect the standard of care you receive.

What will happen to me if I take part?

The study will be discussed with you when you attend the pre-admission clinic at your hospital. Your appointment will be longer than normal so that the study can be explained fully, and you can ask questions to your doctor or nurse.

There will be no difference in your normal standard care leading up to your surgery.

After consenting, you will be asked to complete two short questionnaires (which will take around 5 minutes each) about your health and quality of life. You will be given a signed copy of the consent form and this information sheet to take home with you.

On the day of your surgery, the doctors will use a computer to randomly decide whether you will receive either the volatile anaesthetic or the propofol anaesthetic. Before the surgery starts, a sample of blood (2mls = less than half of a teaspoon) will be taken from your drip.

During your surgery, you will be given the allocated anaesthetic that was randomly assigned to you (either volatile anaesthetic or propofol anaesthetic).

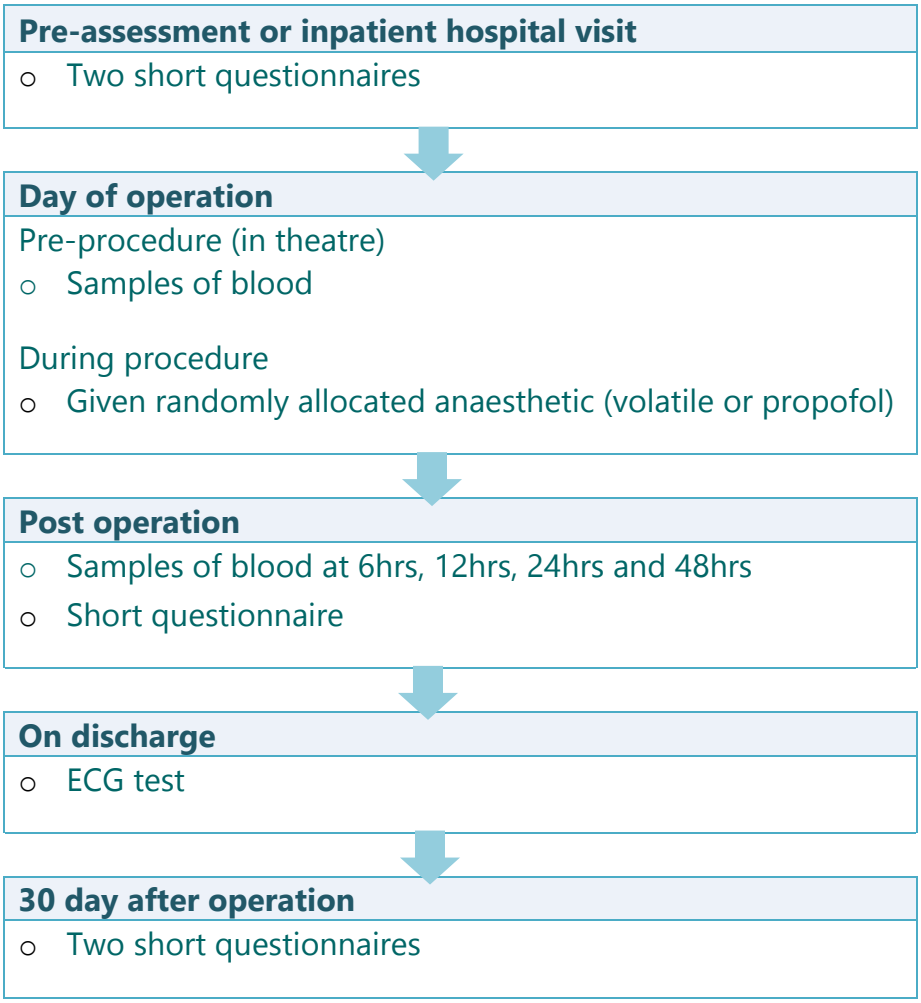
Following your surgery, you will be scheduled to spend some time on the intensive care unit or cardiac recovery room as part of your normal recovery period. You will be given propofol during the recovery period; this is given as part of your normal hospital care. Further blood samples (2mls each) will be taken again from your drip at 6hrs, 12hrs, 24hrs and 48hrs after your procedure so that we are able to assess changes to your heart function.

Three days after your operation, a nurse or doctor will carry out a short questionnaire with you (which will take no longer than 5 minutes) to test whether you suffer from any confusion (also called delirium).

On the day you are discharged from hospital, we will monitor the rhythm of your heart using an ECG (electrocardiogram) test. The test will be carried out with a member of the research team and should take around 5 minutes. When you are discharged from hospital, you will be seen in the outpatients department as part of your normal standard care following heart surgery.

Thirty days after your operation, a nurse will contact you by telephone, email or post to see how you are. They will ask you to complete another two short questionnaires (which will take around 5 minutes each) about your health and quality of life. After this, your involvement in the study will finish.

The flowchart below shows a summary of what taking part would involve:



Are there any risks?

There are no additional risks from joining this study. Both types of anaesthesia (volatile and propofol) have been used as part of routine care for patients for over 30 years.

What are the possible benefits of taking part?

There may not be any direct benefits to you but the information we get from this study might help improve the treatment of people undergoing heart surgery in the future.

What are the possible disadvantages of taking part?

Completing the questionnaires and having an ECG test will take up some of your time. The blood samples will be taken from a drip (central line) which will already be in place for the surgery. You should not feel any discomfort during this part.

What happens when the research study stops?

You will only receive the study anaesthetic (volatile or propofol) during your operation. After

the operation is over you will receive the usual care at your hospital.

The hospital will continue to follow you up in outpatients and treat any conditions or complications if required. The results of the study will be available once all patients have been recruited and completed their follow up.

The results will be published in a medical journal. Once this has happened, if you would like to know which treatment you received or to know the results then please contact the nurse/doctor listed at the bottom of this information sheet.

What if there is a problem?

Any complaint about the way you have been dealt with during the clinical study or any possible harm you might suffer will be addressed. Detailed information concerning this is given in **Part 2** of this information sheet. If you have any concerns or complaints you should contact your study doctor in the first instance.

What are the side effects of any treatment received when taking part?

The known side effects of both of the commonly used anaesthetic drugs are very rare. These include allergic reactions, malignant hyperthermia (a rare febrile reaction to volatile anaesthetics in patients who can be genetically identified), propofol infusion syndrome and unspecific side effects such as a small drop in your blood pressure, which can be immediately corrected by the anaesthetist (by usual practice).

Will my taking part in the study be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. Details are included in **Part 2.**

This completes Part 1 of the Information Sheet.

Thank you for reading. If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decisions.

Part 2

What if relevant new information becomes available?

Sometimes we get relevant new information about the treatment being studied. If this happens, we will tell you about it and discuss whether you want to or should continue in the study.

- If you decide not to carry on, we will make arrangements for your care to continue.
- If you decide to continue in the study we may ask you to sign an updated consent form.
- On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue.

If the study is stopped for any other reason, we will tell you why and arrange your continuing care.

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

You can withdraw at any time but please let the researchers know. Their contact details are on the last page of this document. Information already collected will still be used unless you ask us not to. Any stored blood samples that can still be identified as yours will be destroyed if you wish.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. Their contact details are on the last page of this document.

Every care will be taken in the course of this study. However, in the unlikely event that you are injured by taking part, compensation may be available.

If you suspect that the injury is the result of the Sponsor's (King's College Hospital NHS Foundation Trust) or the hospital's negligence then you may be able to claim compensation. After discussing with your study doctor, please make the claim in writing to Dr Gudrun Kunst who is the Chief Investigator for the clinical study and is based at King's College Hospital.

The Chief Investigator will then pass the claim to the Sponsor's Insurers, via the Sponsor's office. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this.

Participants may also be able to claim compensation for injury caused by participation in this study without the need to prove negligence on the part of King's College Hospital or another party. You should discuss this possibility with your study doctor in the same way as above.

Regardless of this, if you remain unhappy and wish to complain formally, or have any concerns about any aspect of the way you have been approached or treated by members of

staff, or about any side effects (adverse events) you may have experienced due to your participation in the study, the normal National Health Service complaints mechanisms are available to you. Officers from the Patient Advice and Liaison Service (PALS) are available in all hospitals. They offer confidential advice, support and information on health-related matters to patients, their families and their carers. You can find your local PALS office on the PALS website: http://www.pals.nhs.uk/officemapsearch.aspx. Please ask your study doctor if you would like more information on this. Details can also be obtained from the Department of Health website: http://www.dh.gov.uk.

Alternatively, the Independent Complaints Advocacy Service (ICAS) is a national service that supports people who wish to make a complaint about their NHS care or treatment. Contact your local ICAS office through PALS, or ask your research nurse for your local contact number. If you wish you can find your local contact number on the following website: http://www.nhs.uk/choiceintheNHS/ Rightsandpledges/complaints/Pages/ NHScomplaints.aspx

Will my taking part in this study be kept confidential?

If you consent to take part in this study, the records obtained while you are in this study, as well as related health records, will remain strictly confidential at all times. The information will be held securely on paper and electronically at your treating hospital and the main hospital site managing this research under the provisions of the 2018 Data Protection Act. Your name will not be passed to anyone else outside the research team or the Sponsor, who is not involved in the study.

How will my data be managed and stored?

King's College Hospital NHS Foundation Trust 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. King's College Hospital will keep identifiable information about you for five 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 on the following website: https://www.kch.nhs.uk/about/corporate/ data-protection.

Your treating hospital will collect information from you and your medical records for this research study in accordance with our instructions.

Your treating hospital will keep your name, NHS number and contact details confidential and will not pass this information to the sponsor (King's College Hospital NHS Foundation Trust). The hospital will use this information as needed, 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. Certain individuals from King's College Hospital and regulatory organisations may look at your medical and research records to check the accuracy of the research study. King's College Hospital will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.

The research team will keep identifiable information about you from this study for five years after the study has finished.

In line with the regulations, at the end of the study the research data will be securely archived for 15 years.

Will my GP be informed of my involvement?

With your permission, your GP and other doctors who may be treating you will be notified that you are taking part in this study. There will be no other information passed onto them.

What will happen to any samples I give?

Any blood samples that are taken as part of the research study will be taken at your local hospital and transferred to a central laboratory for further analysis of the function of your heart muscle (by a simple biomarker test of a marker called Myosin binding Protein C). The blood will be anonymised and will only be identified by using your unique study number. All results will be sent to the statistician who is based at the London School of Hygiene and Tropical Medicine (LSHTM). You will not be told of the results of these study specific blood tests. Unless you withdraw your consent, we will ask you to gift your blood to the people running the study and in so doing give up all future claims to its use that may include further research with biomarker tests (details of this will be defined in the future). The samples will not be transferred outside of the UK.

What will happen to the results of the research study?

The results of the study will be available after it finishes and will be published in a medical journal and be presented at a scientific conference. The data will be anonymous and none of the patients involved in the study will be identified in any report or publication. If you wish to see the results, or the publication, please ask your doctor.

Who is organising and funding the research?

The research is being organised by King's College Hospital NHS Foundation Trust. However, the management of the study is being done at LSHTM (London School of Hygiene &

Tropical Medicine) and King's Health Partners Clinical Trials Office (KHP-CTO), who are experienced in running studies like this. The funding for COPIA is a grant from the National Institute of Academic Anaesthesia. Your own doctor does not get paid anything directly for putting you into this study.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by London-Chelsea Research Ethics Committee.

Further information and contact details

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the drug involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor.

If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Details of how to contact the research team:

Insert contact details of PI and research nurses here

Thank you for taking the time to read this information sheet and to consider this study.

Please refer to the study website for more information: **copia.lshtm.ac.uk**