Imperial College Healthcare
NHS Trust

PATIENT INFORMATION SHEET

Title: **Identifying autonomic drivers for human Atrial Fibrillation**

Chief Investigator Professor Prapa Kanagaratnam
Study Sponsor: Imperial College London
Co-ordinating site Hammersmith Hospital
PIS Version number Version 1, 11/06/2019
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INVITATION

You have been invited to participate in a research study. Before you decide, it is important you understand the background to the study, why it is being performed, what it will involve and the potential risks and benefits. Please take your time and read the below information carefully. Do not hesitate to contact your doctor or a member of the research team if you have any questions.

WHAT IS THE STUDY BACKGROUND?

We know that the heart rhythm problem called Atrial Fibrillation (AF) is caused by abnormal electrical currents in the small chambers of the heart termed the atria. Landmark studies have shown that in about half of people with AF, these abnormal electrical currents originate from the pulmonary veins, which join the left atrium to the lungs. A procedure called 'pulmonary vein isolation' (PVI) is done using catheters inside the heart that are introduced through the blood vessels in the groin. Once inside the left atrium, the catheters are used to make small burns along the base of the pulmonary veins where they join the heart to prevent the abnormal electrical currents from reaching the rest of the atria. This prevents AF in about 50% of people. However, the PVI procedure that we perform is not tailored to each individual patient and we don't know exactly why it works.
A different approach is to target the nerve cells in the atria called ganglionated plexi (GPs). It is thought that these GPs trigger AF and so ablating the GP could be more effective than PVI. They are often found at the base of the pulmonary veins, and also within the atria. Our group has developed a method for locating these GPs and have shown that ablating GP sites can prevent AF. This work has been done mainly in patients who are in normal rhythm most of the time (paroxysmal AF). We have now developed the method for detecting GP sites so it can be used in people who are in AF all of the time (so called persistent AF).

This project will be unique in being able to locate the nerve cells that trigger AF in patients with persistent AF. We then plan to ablate them and hope that this will reduce the recurrence of AF after the procedure. We hope this detailed understanding of the triggers of AF will lead to a new treatment option for patients.

The research will be undertaken by Dr Clare Coyle as a part of her PhD thesis. She will be guided by Professor Prapa Kanagaratnam from the National Heart and Lung Institute with input from Dr Nicholas Linton from the Department of Bioengineering at Imperial College London. The procedures will take place at Imperial College Healthcare NHS Trust.
Patients who have been recommended AF ablation by their doctor will be offered the chance to participate in the study and followed up for a year afterwards.

WHY IS THE STUDY BEING DONE AND WHAT IS BEING TESTED?

The aim of the study is to locate the GP sites in patients with persistent Atrial Fibrillation. These will be ablated and patients followed up to see if this reduces the recurrence of Atrial Fibrillation. We hope that this will lead to improved treatments for patients suffering from persistent AF.

WHAT WILL HAPPEN TO ME IF I DECIDE TO PARTICIPATE?

First, you will be screened for eligibility in the study. This will involve a doctor or nurse asking you questions about your medical history and the medications you take. A doctor will also briefly examine you. If you are deemed eligible, your ablation procedure will be scheduled. You will need to take a medication, Amiodarone, for 6 weeks prior to your procedure. This is to try and keep the heart in a normal rhythm to make mapping of the heart easier on the day of the ablation. You will receive further information on the research protocol and will have the opportunity to review this and discuss any questions with the research team either over the phone or in person. On the day of the procedure, you will be reviewed again by the research team with another opportunity to ask any questions, and then informed consent will be obtained. You will have the ablation procedure (see section below for further details) and then receive the usual follow up which includes outpatient clinic review and four outpatient 24 hour heart monitors (called Holters) at 3, 6, 9, & 12 months to assess whether the AF has returned.

WHAT WILL HAPPEN TO ME ON THE DAY OF THE ABLATION PROCEDURE?

You will arrive at hospital and be reviewed by the anaesthetist, operating Cardiologist and research Doctor. You should ask as many questions as you feel you need to. If you are happy to proceed with the research then informed consent will be obtained. It is important to note that the two consent processes are separate and so agreeing to have the routine AF ablation procedure does not bind you to participating in the research.

As per normal procedure, the ablation treatment will be performed under a general anaesthetic. All patients have a transoesophageal echo once they are asleep to make sure there is no blood clot in the heart before starting the procedure. If a blood clot is found then the procedure will have to be abandoned as there is a risk of stroke. Once you are asleep, the doctors will insert the catheters into the blood vessels in your groin to gain access to the heart.

As part of the research protocol, you will have mapping of the left atrium of the heart with high frequency stimulation to look for GPs. These will be ablated when found. The location of the ablation will therefore be different to the routine PVI procedure but the technique for performing the ablation will be the same. From our work performing this procedure in patients with paroxysmal AF, this technique can take up to an hour longer than a routine PVI procedure but typically requires fewer burns. The research procedure is expected to have an identical risk profile to the routine PVI procedure as the same equipment and ablation techniques will be used, only the location of the ablation will vary. Your experience of the procedure would be exactly the same.

These procedures use ionising radiation. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chances of this happening to you are the same in the research procedure as compared to the routine PVI procedure.

WHAT DO I NEED TO DO IF I DECIDE TO TAKE PART?

You need to be able to attend on a specific day for your procedure and to attend regular follow up afterwards. This includes outpatient 24 hour heart rhythm monitors at 3, 6, 9 and 12 months post procedure. You would need to attend one of the Imperial College NHS Trust Hospitals to have this fitted, wear it for 24 hours, and then drop it back to the same Hospital the next day. This records your heart rhythm so that we can tell whether you are in a normal heart rhythm or not. There will also be two outpatient clinic appointments where you will be reviewed by your Doctor to ensure you have recovered from your procedure and to assess your heart rhythm.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Participating in this research will increase our understanding of the location & function of the nerve cells (GP) in the heart, and help us to understand their role in triggering and maintaining AF. Our preliminary research looking at patients with paroxysmal AF suggests that ablating the GPs is at least as good as the standard PVI procedure, and with less tissue injury. We hope to confirm these preliminary findings and assess whether there may be improved outcomes compared to PVI. Participants will also receive the benefit of increased monitoring during follow up through additional access to the research staff which enables review of any home ECG monitoring they may have and follow up of symptoms.

WHAT ARE THE POSSIBLE RISKS OF TAKING PART?

The risks of this research study are incurred during the catheter ablation procedure. The risks of a catheter ablation procedure are not affected by the GP mapping. The

mapping protocol may increase the length of time that the overall procedure takes, by up to an hour, but this is still within a normal range for the time taken to complete an ablation procedure as the duration varies from patient to patient. A procedure using conventional mapping and a procedure undertaken as part of the research protocol are expected to have an identical risk profile as the same equipment and ablation techniques will be used, but the location of the ablation will vary.
The risks of undergoing an AF ablation procedure, whether the routine PVI or the research study, are;

1 in 100 cases may have vascular problems including bleeding from the groin. This may require prolonged pressure or an injection to stop the bleeding.

1 in 200 risk of stroke. This can cause slurred speech, weakness, or loss of vision. Most symptoms will resolve within 24 hours but some can cause permanent disability.

1 in 100 risk of fluid around the heart (pericardial effusion) which will require treatment with a drain which usually stays in place for 24 hours.

1 in 1000 risk of nerve damage, including the nerves that supply the diaphragm. This can take up to 6 months to recover.

1 in 5000 risk of damage to the oesophagus. This can cause pain, difficulty swallowing and stroke.

1 in 1000 risk of permanent pacemaker.

1 in 1000 risk of death.

There will be further opportunity to discuss these risks before and on the day of the procedure.

WILL MY PERSONAL INFORMATION BE KEPT CONFIDENTIAL DURING THIS STUDY?

Imperial College 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. Imperial College London will keep identifiable information about you for 10 years after the study has finished in relation to data subject consent forms and primary research data. This will be stored at Imperial College Healthcare NHS Trust.

Further information on Imperial College London's retention periods may be found at https://www.imperial.ac.uk/media/imperial-college/administration-and-support-services/records-and-archives/public/RetentionSchedule.pdf

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 by contacting the Principal investigator Prof Prapa Kanagaratnam on p.kanagaratnam@imperial.ac.uk or via switchboard on 020 3313 1000.

LEGAL BASIS

As a University we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

INTERNATIONAL TRANSFERS

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

CONTACT US

If you wish to raise a complaint on how we have handled your personal data or if you want to find out more about how we use your information, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

Imperial College Healthcare NHS site will collect information from you and your medical records for this research study in accordance with our instructions.

Imperial College Healthcare NHS Trust will keep your name, NHS number and contact details confidential and will not pass this information to Imperial College London. Imperial College Healthcare NHS Trust 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 Imperial College London and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Imperial College London 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.

Imperial College Healthcare NHS Trust will keep identifiable information about you from this study for 10 years after the study has finished.

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies 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. This information will not identify you and will not be combined with other information in a way that could identify you. 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 decisions about future services available to you, such as insurance.

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

At the end of the study, your care will continue in a routine manner. You will also receive continuing care from your GP. You can withdraw from the research trial at any point; you do not need to explain why, but can should you wish to. The information collected about you during the time you were enrolled in the study may be used toward the study analysis if you give consent for this.

WHAT HAPPENS IF I WANT TO EXIT THE STUDY BEFORE IT ENDS?

You can withdraw participation at any point in the study. You may be contacted by the research team to discuss the reasons for which you are withdrawing, but you are not obliged to disclose these. If you are later unable to provide informed consent for ongoing participation in follow up, the data already collected with consent will be retained and used in the study but no further data will be collected and no further research procedures carried out.

HOW WILL I KNOW OF THE STUDY'S RESULTS?

The research team will contact you with the results of the study. Additionally, the results will be submitted for publication in peer-reviewed medical journals and conferences.

WHO IS FUNDING THE STUDY?

The study is sponsored by Imperial College and funding comes from local research funds. The investigators are physicians funded by the National Health Service.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed and approved by the South Central- Berkshire Research Ethics Committee

ADDITIONAL INFORMATION

This study forms part of the research required for a PhD candidate at Imperial College London.

WHAT IF SOMETHING GOES WRONG?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator Prof Prapa Kanagaratnam on p.kanagaratnam@imperial.ac.uk or via switchboard on 020 3313 1000. The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Joint Research Compliance Office

PALS: The patient advice and liaison service can be contacted on imperial.pals@nhs.net or 020 3313 3322 Monday to Friday 9am to 5pm.

WHO DO I CONTACT FOR FURTHER STUDY INFORMATION?

Should you have any further questions about the study or the study products, or in case of an emergency please contact:

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Fax: 02078861657
Emergency contact number: 07985 352148
Email address: clare.coyle@nhs.net

Thank you for reading this information leaflet. Please feel free to contact us if you require further information or clarification.

Please keep this copy of the information sheet and a signed consent form.