

Chief investigator: Dr Tim Betts

Co-investigator and lead contact: Dr Michael Pope

Contact: Research Fellow Office,

Dept. Cardiology,

John Radcliffe Hospital,

Oxford

OX3 9DU

Tel: 01865 220255

**PARTICIPANT INFORMATION SHEET**

**Biatrial global high-density electroanatomical mapping of atrial fibrillation – a prospective mechanistic registry study (BiMAP-AF)**

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please ask us.

# What is the purpose of the study?

We are aiming to develop understanding of the electrical mechanisms of atrial fibrillation in order to improve the effectiveness of ablation procedures particularly for patients with persistent rhythm disturbances. We plan to examine the electrical activity in both upper chambers of the heart and explore how these interact with each other.

# Why have I been invited?

You are being invited to participate in this study because you suffer from atrial fibrillation and together with your cardiologist have decided to undergo a catheter ablation procedure. We are aiming to recruit 22 patients in the same position as you.

# Do I have to take part?

No, taking part is entirely voluntary. You are free to withdraw if you later change your mind, without giving a reason and withdrawal will not affect your clinical care. Although this research study would form an additional part of your ablation procedure, if you decide not to participate then your procedure will still go ahead as normal.

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

Importantly, taking part in this research does not affect any of the standard care that you receive when undergoing your ablation procedure.. Any tests that your consultant arranges as part of standard care, such as blood tests or imaging by ultrasound, CT or MRI will all still take place as planned in advance of the catheter ablation procedure. The results of these tests will be collected as part of the study.

If you agree to take part, then a member of the research team will meet with you. We will aim to schedule this to coincide with when you attend the hospital for other tests or at the time of pre-assessment prior to the procedure. At this point we will make sure you understand the study fully and ask you to sign the consent form as well as collect information about your past medical history, medications, height, weight, and a simple clinical examination.

When you attend for your ablation procedure, this will largely be carried out in the standard way. That includes use of a general anaesthetic and passing a number of wires (known as catheters) into the veins at the top of the leg before they are manoeuvred into the heart. A procedure called a trans-septal puncture is performed to cross from the right side of the heart to the left side and you will be given blood-thinning medication intravenously (through a drip into the veins), as is standard.

In most standard procedures, the electrical recordings (mapping) and ablation that is then carried out is on the left side of the heart. In this study, we will use one extra catheter, which will be placed in the right side of the heart and allow electrical recording on both sides of the heart at the same time. It is this additional catheter and the recordings from both heart chambers that form the basis of this research study. The doctor carrying out the ablation will then proceed as they normally would and target any areas for ablation that they deem necessary. Further electrical recordings will be taken at repeated times during the procedure and we will collect recordings whilst stimulating the heart to beat at different heart rates. This is done through the wires placed in the heart as part of a normal.

When the procedure is finished you will be looked after in hospital and discharged in the normal way. You will then be seen for a follow up appointment 3 months later, which is standard practice. One of the members of the research team will also see you at this point to see how you are, check your medications and record an ECG. We will then see you again 9-12 months after your procedure and try to schedule this alongside visits to the hospital for standard follow up appointments. You will be seen by a member of the research team who will record a further ECG, ask about any symptoms you may have had, and check your medications. Around the same time, we will also arrange for you to wear a 72-hour heart monitor. This will be fitted in the hospital with instructions given to you and you will then wear it until dropping it off in the hospital. This will constitute the end of your involvement in the study.

# What should I consider?

Most people undergoing an ablation procedure for atrial fibrillation are able to take part. However if you have had an ablation procedure in the past or have had surgery on your heart then you will not be eligible (stent insertions for coronary artery disease causing angina or a heart attack, or having a pacemaker are not a problem). The only other situations in which you would not be eligible are if you are pregnant, breast feeding, or planning pregnancy at the time of the procedure, involved in a separate research trial using a study medication, or it was felt there may be an anatomical problem that meant the second mapping catheter could not be used. If you are not sure about any of this then please ask.

# Are there any possible disadvantages or risks from taking part?

The catheter ablation procedure itself carries a degree of risk, irrespective of participation in the trial and, in advance of the procedure, your doctor will explain these to you in detail. The only additional intervention is the use of a second mapping catheter. This will add little to the overall risk but will add approximately 30 minutes to the length of the procedure. It will require a further area of access to the veins in the top of the leg and will pass through an additional sheath (tube in the vein). This has some risk of bruising and bleeding and damage to nearby structures such as the artery, but no more so than each of the standard tubes that have already been placed in there. The catheters for the case are manoeuvred into position under X-ray guidance. This is standard practice and therefore involves exposure to radiation, which is kept as low as possible. The second mapping catheter used in this study is positioned in the same way.

**Radiation Risk**

The catheter ablation procedures are part of your routine care. If you take part in this study you will not undergo any additional procedures. These procedures use ionising radiation to form images of your body. 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 whether you take part in this study or not.

# What are the possible benefits of taking part?

There are no clear benefits to you of taking part. It may be that the extra electrical information generated allows better targeted ablation but this is not yet known. It is hoped that the information generated from this study will help future patients, and of course if you ever needed a further procedure in the future then this could be you. The follow up visits with the research team after the procedure are in addition to standard clinic visits and you may find these helpful.

# Will my General Practitioner/family doctor (GP) be informed of my participation?

GPs will not be routinely notified of study participation but there may be instances where GPs will be contacted to follow up incidental findings that may be of clinical significance, such as high blood pressure or indications of depression.

# Will my taking part in the study be kept confidential?

All of the clinical data that is collected is contributing to the catheter ablation procedure you are undertaking. All of this is stored on secure hospital servers in keeping with standard care. Data that is then extracted as part of the study, including the mapping data will then be fully anonymised and stored according to study code only. This will also be stored on secure servers at all times.

Responsible members of the Oxford University Hospitals NHS Foundation Trust may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

# Will I be reimbursed for taking part?

There should not be any cost to you of taking part in the study. Whenever possible, we will time research visits to coincide with attendance at the hospital for clinical appointments. If this is not possible we will reimburse travel costs.

# What will happen to my data?

Electrical mapping data and other clinical data will be kept in an anonymised form and may be analysed in the future as either an extension to this study or in future research. This anonymised data will be used mainly by local researchers, but ethically approved research projects may take place in hospitals, universities, non-profit institutions or commercial centres worldwide. As is noted above, all of this data will be kept highly confidential.

We will be using information from you and your medical records in order to undertake this study. Research is a task that we perform in the public interest. Oxford University Hospitals NHS Foundation Trust, as sponsor, is the data controller. This means that we, as Oxford University Hospitals NHS Foundation Trust researchers, are responsible for looking after your information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about you for 12 months after the study has finished. We will store the anonymised research data and any research documents with personal information, such as consent forms, securely at the Oxford University Hospitals NHS Foundation Trust for 5 years after the end of the study.

Oxford University Hospitals NHS Foundation Trust will use your name, NHS number, home address, and contact details 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. They will keep identifiable information about you from this study for 12 months after the study has finished.

Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

You can find out more about how we use your information by contacting the research team on the details below.

# [What will happen if I don't want to carry on with the study?](http://hra-decisiontools.org.uk/consent/content-sheet-support.html" \l "two)

Participation is entirely voluntary and you may change your mind at a later stage. If this is the case then you are free to withdraw from the study at any point. This will not in any way affect the clinical care that you receive. If you withdraw in advance of the ablation procedure, then no data will be collected and any clinical results recorded at that stage will be destroyed. If you withdraw after the procedure then the data collected will still be analysed. This will not affect your clinical follow up but you will not receive any follow up as part of the study.

# What will happen to the results of this study?

It is hoped to publish the results of this study in academic journals and present the data at conferences. None of the study participants will be identified through any of this. If you wish, you can be provided with any results published.

# What if we find something unexpected?

In the unlikely event that something unexpected is found during the study or follow up visits then this will be evaluated as appropriate including through liaising with your General Practitioner.

# What if there is a problem?

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the Chief Investigator, Dr Timothy Betts (phone number: 01865 220256 & email: drbetts.pa@ouh.nhs.uk) or the co-investigator, Dr Michael Pope (phone number: 01865 220255 & email: Michael.pope@ouh.nhs.uk).

There are no special compensation arrangements. Oxford University Hospitals NHS Foundation Trust will provide indemnity for this study. If you are harmed due to someone’s negligence, then you may have grounds for legal action but you may have to pay for it.

NHS bodies are legally liable for the negligent acts and omissions of their employees. If you are harmed whilst taking part in a clinical trial as a result of negligence on the part of a member of the study team this liability cover would apply.

Non-negligent harm is not covered by the NHS indemnity scheme. The Oxford University Hospitals NHS Foundation Trust, therefore, cannot agree in advance to pay compensation in these circumstances. In exceptional circumstances an ex-gratia payment may be offered.

You will also be able to contact the Patient Advice and Liaison Service (PALS) in the first instance (01865 221473).

# How have patients and the public been involved in this study?

Patients have not directly been involved in designing this study but have been at the forefront of considerations at every step. Further general information about taking part in research can be found at the following websites:

* www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
* www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

# Who is organising and funding the study?

The study is being arranged by researchers in the Division of Cardiovascular Sciences within the Radcliffe Department of Medicine at Oxford University Hospital NHS Foundation Trust. The study is sponsored by the Oxford University Hospital NHS Foundation Trust. Funding is through departmental research budgets. Further funding has been applied for through a medical research charity grant. No doctor or member of the research team is being paid to participate. No member of the research team has any financial relationship with commercial companies related to the 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 participants’ interests. This study has been reviewed and given favourable opinion by South Central – Hampshire A Research Ethics Committee.

**Further information and contact details:**­

Please contact Dr Michael Pope by e-mail: [Michael.pope@ouh.nhs.uk](mailto:Michael.pope@ouh.nhs.uk) or in writing: Research Fellow Office, Department of Cardiology, John Radcliffe Hospital, Headley Way, Oxford, OX3 9DU, or by telephone 01865 220255