Patient Information Sheet
Opportunistic Detection of Atrial Fibrillation in Ambulatory Blood Pressure Monitoring
Atrial Fibrillation Group

We'd like to invite you to take part in our research study. Before you decide if you would like to take part we would like you to understand why the research is being done and what it would involve for you. One of our team will go through this information sheet with you and will answer any questions you may have. Please don't hesitate to contact us if you would like more information or if anything is unclear.

What is the purpose of this study and why have I been invited to participate?

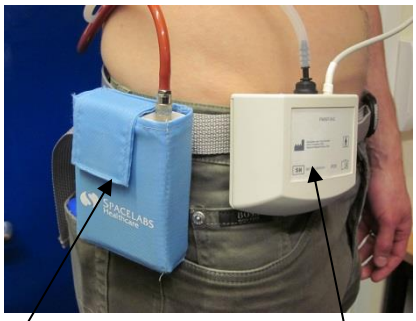
The purpose of this study is to assess the value of a new method for atrial fibrillation screening. For this we need to collect data from a group of participants known to have atrial fibrillation. We are inviting you to take part in this study because you have previously been diagnosed with atrial fibrillation. Atrial fibrillation is a heart condition that causes an irregular and often abnormally fast heart rate (NHS choices, 2014). People with atrial fibrillation are at an increased risk of stroke and heart disease. There is currently no national screening programme for atrial fibrillation, but checking for it during blood pressure measurement has been found to be effective. Ambulatory blood pressure measurement is a common investigation and involves taking multiple blood pressure measurements over 24 hours. This would give multiple opportunities for detecting atrial fibrillation. This may allow us to detect atrial fibrillation earlier in some patients which would allow them to access treatments sooner and increase their chances of long term survival.

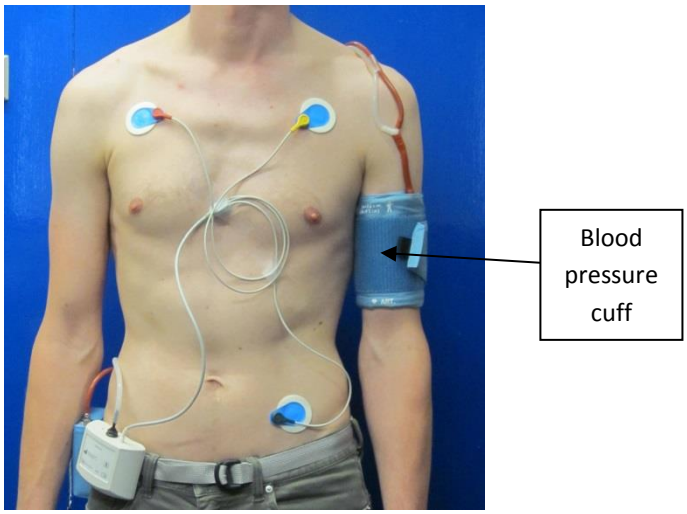
Do I have to take part?

No, it's completely up to you. If you do decide to take part then you will be asked to sign a consent form. You are free to withdraw from the study at any time without giving a reason.

What would taking part involve?

If you agree to take part we will ask you to sign a consent form. We will then ask you to wear an ambulatory blood pressure monitor for three hours. The monitor consists of a small, lightweight recorder attached to a blood pressure cuff which is wrapped around your upper arm. Every 15 minutes the cuff will inflate to a set pressure and then gradually deflate while it takes a reading of your blood pressure. Additionally we will ask you to wear a second device consisting of another small, lightweight recorder attached to three sticky pads which will be placed on your chest as can be seen in the pictures below. These pads will be placed on your chest and will be used to monitor your heart rhythm over the three hours. The device will also be connected to your blood pressure recorder. After we have set up the equipment you can replace your clothing and you will be free to leave the hospital. After the three hours are over we will ask you to return to the department where we will disconnect both devices.





What are the possible benefits of taking part?

We cannot promise that this study will benefit you directly. However, the results of this study may benefit patients undergoing ambulatory blood pressure monitoring in the future.

What are the possible disadvantages and risks of taking part?

There are no serious risks involved in this study. You may feel some temporary discomfort when the cuff inflates. Also, we may have to shave small parts of your chest to place the sticky pads and there is a chance you may have a skin reaction to this.

What if an unknown clinical condition is discovered?

If an abnormal condition is detected we will send a letter to your referring clinician provided you give us permission to do so. If appropriate you may also be contacted by a hospital consultant.

What if something goes wrong?

This is highly unlikely for this study. In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you. You will not be liable for accidental damage.

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study please contact the research team in the first instance. If you feel the research team was unable to satisfactorily resolve your complaint you can contact the Patient Advice and Liaison Service for independent advice using the details below:

Tel: 0800 032 02 02
Email: northoftynepals@nhct.nhs.uk

Will my information be kept confidential?

All data collected during this study will be kept confidential.

We will collect data on your age, gender and current medication for this study. This information will be kept in a secure location. It will allow us to assess how these factors influence the results of the study and will only be accessible by the study team. Any data which could identify you as a participant in this study (name, age, gender and medication) will be disposed of confidentially one year after the study has finished.

The research data from your blood pressure monitor and your heart rhythm recordings will also be kept secure. This data will be kept separately from any data that could identify you; however it will have a code which we can link to you if any abnormal results are found. This data will only be accessible by the

study team and, if necessary, your direct care team. This data will be disposed of confidentially five years after the study has finished.

What will happen to the results of this study?

The results will be analysed and published in scientific journals. Individual data will not be identifiable in any paper or report. A summary of the results will also be posted on our study website, research.ncl.ac.uk/opafib, once the study is complete and all the results have been analysed.

Will I receive any incentives for taking part in this study?

We are not able to offer incentives for this study. However we are happy to reimburse any reasonable additional costs you incur as a result of taking part such as food and travel costs if you provide the relevant receipts/tickets to the researcher following the study.

Who is organising and funding this study?

This study has been organised by the Newcastle upon Tyne NHS Foundation Trust and has been funded by the Newcastle NIHR Biomedical Research Centre.

Who has reviewed this 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 the York Research Ethics Committee.

What should I do now if I want to take part?

If you would like to take part in this study please contact a member of our research team. We will arrange a suitable time for you to take part in the study.

Contact Details

For further details, or if you have any questions, please feel free to contact:

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Or take a look at our website: research.ncl.ac.uk/opafib