

Patient Information Sheet

Opportunistic Detection of Atrial Fibrillation in Ambulatory Blood Pressure Monitoring

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. Please take the time to read through this information sheet and talk to others about the study if you wish. One of our team will be available to talk to you on the day of your 24 hour blood pressure appointment if you decide you would like to take part or want more information. Please don't hesitate to contact us if you would like more information before then or if anything is unclear.

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

We are inviting you to take part in this study because you have been referred for a 24 hour ambulatory blood pressure test and because you have no history of 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, but are often undiagnosed. In future, one new way to detect atrial fibrillation is during blood pressure measurement. Ambulatory blood pressure measurement involves taking multiple blood pressure measurements over 24 hours, giving 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.

We have developed a new technique for detecting atrial fibrillation during blood pressure monitoring, but we want to be sure that it does not give positive readings on people without atrial fibrillation.

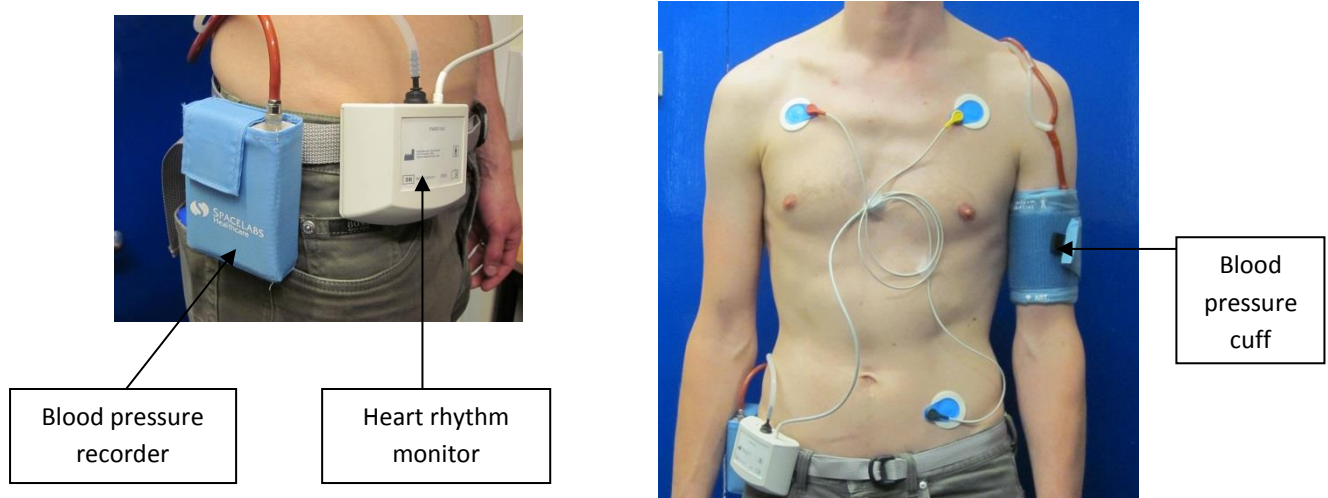
Do I have to take part?

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. If you decide not to take part or to withdraw from the study this will not affect the standard of care you receive.

What would taking part involve?

You are already scheduled to have a routine 24 hour ambulatory blood pressure monitoring test for which you will be asked to wear a blood pressure recorder over 24 hours. If you agree to take part in this study then we will ask you to also wear a second monitor over the same 24 hours. This monitor is very small and lightweight and can clip on to a belt. The monitor will be connected by a wire to three sticky pads which will be placed on your chest as can be seen in the pictures below. These will be used to monitor your heart rhythm. The monitor 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 test we will ask you to disconnect the monitor and return it to the hospital along with the blood pressure recorder.



What are the possible benefits of taking part?

There is a chance that we may find that you have atrial fibrillation that was previously undetected. This would allow you to begin any treatments earlier than you may do otherwise. Additionally, the results of this study may benefit other patients having ambulatory blood pressure tests in the future.

What are the possible disadvantages and risks of taking part?

There are no serious risks involved in this study. There is a small possibility that the use of the second device may cause an error in your blood pressure

measurements. In this case the test may have to be repeated. We have taken all possible precautions to minimise this risk. 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. If you learn that you have a previously unknown condition after taking part in this study you can seek advice from your clinician or alternatively you can contact the Patient Advice and Liaison Service for support using the below details:

Tel: 0800 032 02 02

Email: northoftynepals@nhct.nhs.uk

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 and gender 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 and gender) 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. Your 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.

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?

A member of our research team will be available to talk to you on the day of your appointment and will ask if you would like to take part in the study. If you would like to ask any questions before then please contact us using the details below.

Contact Details

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

Miss Sarah Kane
Research Scientist
Medical Physics
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
NE1 4LP
Tel: 0191 2825174
Email: sarah.kane@nuth.nhs.uk

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