

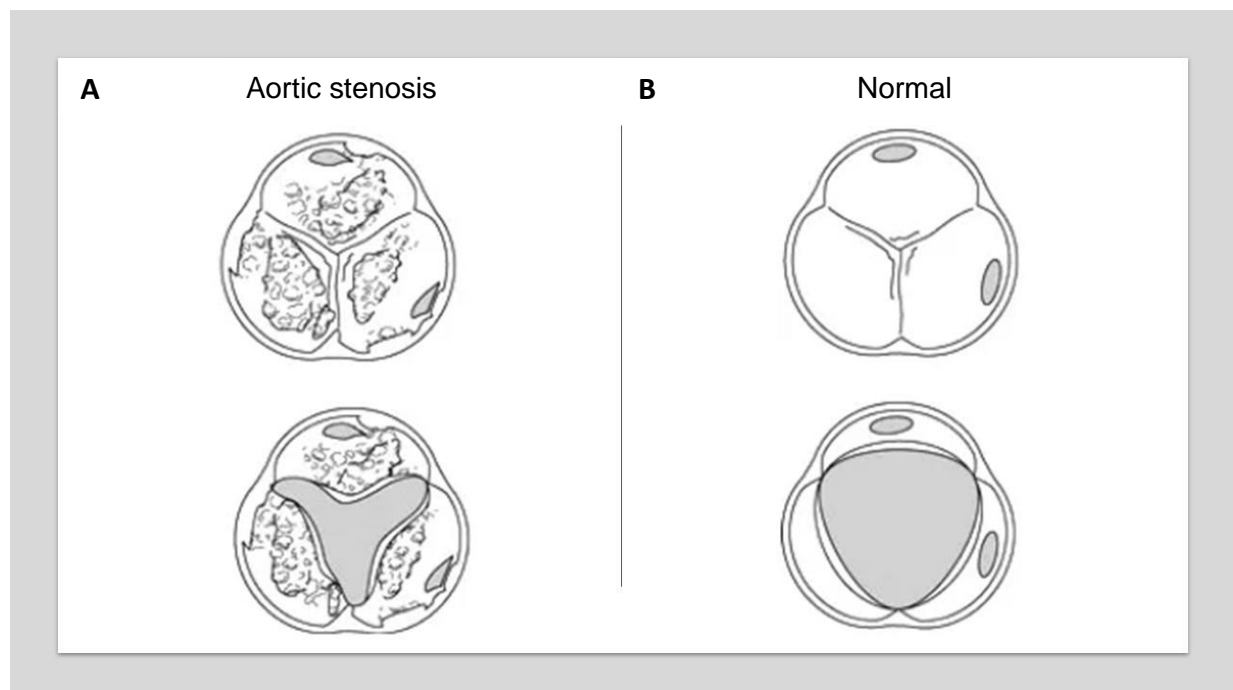
## Myocardial Work in Severe Aortic Stenosis:

### Participant Information Sheet

We would like you to take part in our research study. Before you decide, it is important that you understand why the research is being carried out and what it will involve. Please read the information provided and discuss this with others including family members or friends if you wish. If you would like more information, please don't hesitate to ask us.

#### What is the purpose of the study?

You have been invited to the Freeman Hospital to have a heart valve replacement for aortic stenosis. Aortic stenosis is caused by thickening of a heart valve over time which means it doesn't open very well (*image one*), reducing your quality of life. With the use of echocardiograms, we plan to assess how your heart responds following treatment for aortic stenosis. The aim of the study is to identify if the use of a new technique known as Myocardial Work can predict how successful valve replacement will be for patients. This information could provide more detail identifying when the procedure could occur in future patients with aortic stenosis.



*Image one: (A) shows a thickened aortic valve with reduced opening consistent with aortic stenosis. (B) Normal aortic valve which opens well showing no aortic stenosis.*



### **Why have I been invited to participate in the study?**

You have been invited to participate in the study as you have significant aortic stenosis and are receiving a replacement valve soon. By studying the Myocardial Work in patients with aortic stenosis, we can use this information to help identify people who are higher risk of rehospitalisation and early mortality. We plan on inviting as many people as possible with aortic stenosis who have been scheduled for a replacement valve to be involved in the trial over a two-year period. The study is part of a PhD qualification at Newcastle University and will follow-up participants over three years after the valve implantation.

### **Do I have to take part?**

You do not have to take part... Taking part in the trial is completely voluntary and you can withdraw at any time without reason. You will still receive excellent care regardless if you wish to take part, decline or withdraw from the study at any time. Your treatment will not change if you are involved in the study or not.

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

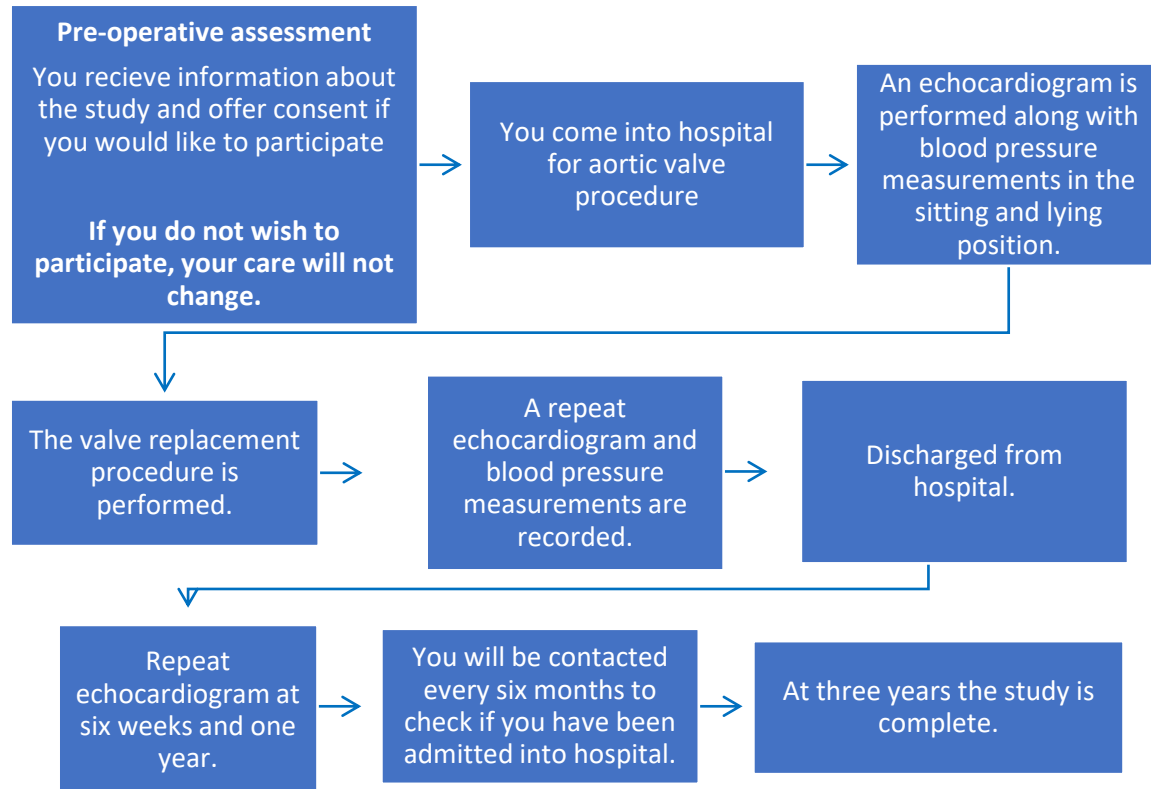
If you agree to participate, a standard echocardiogram will be performed similar to what you have experienced previously to get some baseline measurements. Your blood pressure will also be measured while sat upright before your scan and while laying down after your scan. You will then proceed to receive your replacement valve to treat the aortic stenosis. Once you have returned from the procedure, a second echocardiogram will be performed to look at your heart function and check the valve is working well. Your blood pressure will be monitored and recorded before and after your scan.

You will be invited back to the hospital at around **six weeks** and at **one year** for repeat echocardiograms following your valve replacement – While this is standard practice, we will use the images collected from the scan and repeat your blood pressure once again to calculate Myocardial Work.

Myocardial Work will be calculated at Newcastle University after your echocardiogram has been performed by the study lead in the hospital clinic. As the Myocardial Work analysis is done after your echocardiogram, there are no changes in how the images are taken.

You will be contacted by the study lead **every six months** by your preferred contact method (phone or letter) for up to three years after your valve replacement. You will be asked if you have recently been admitted into hospital within the last six months. If so, were you admitted into hospital due to symptoms caused by heart failure, stroke or heart attack?

The flow chart below details what is involved in the research study:



### What should I consider?

You should continue to take your regular medication prescribed by your doctor. If the image quality seen during the echocardiogram affects the ability to make accurate measurements, then you may not be suitable to take part in the study – this will not impact on your treatment.

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

Echocardiography and blood pressure measurements are completely safe and non-invasive tests. Occasionally, a patient may feel mild discomfort during an echocardiogram where the probe is placed on the chest but should not be painful. You will be contacted every six months to identify if you've been unexpectedly admitted into hospital.

### What are the benefits of taking part?

The data collected from the study will offer more information about how the heart behaves after a valve procedure to help future patients with your condition. While this study may not directly benefit you, the results may change practice to help future patients with aortic stenosis.



**Will my General Practitioner/Family Doctor be informed of my participation?**

Your registered General Practitioner/family doctor will not be informed of your participation in the study. They may be contacted with your permission if there are important incidental findings such as high blood pressure noted during the follow-up period. Any incidental findings seen on subsequent echocardiograms will be forwarded to the consultant who is responsible for your care.

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

Yes, your information will be kept confidential. For the study, your personal information will be completely anonymised and replaced with a study code specific to you meaning this will be non-identifiable. This does mean that if you withdraw from the study your data cannot be withdrawn. Responsible members of the Newcastle 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. We will request your permission to use anonymised data for future analysis. This will be optional and will not affect your participation in the study. The London-Chelsea Research Ethics Committee has given a favourable opinion of the study.

In this research study we will use information from you, your medical records and your echocardiogram images. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. We will make sure no-one can work out who you are from the reports we write.

**What will happen if I choose not to carry on with the study?**

You can withdraw from the study at any time. Participation is completely voluntary, and withdrawal will not affect or change the care you receive. To withdraw from the study please contact Peter Luke via email on [peter.luke@newcastle.ac.uk](mailto:peter.luke@newcastle.ac.uk). You can also contact Peter by phone on 07845199255 who is the study lead and inform him that you are withdrawing from the study.

**What will happen at the end of the study?**

You will be informed of the results at the end of the study using your preferential method of contact. All participants will be invited to a virtual meeting to discuss the findings of the study as a group.



**Will I receive payment for my involvement in the study?**

You will receive expenses to cover all associated costs for your travel to the hospital for the 6 week and 12-month follow-up echocardiograms at Newcastle Hospitals Trust.

**Making a complaint.**

If you prefer to raise your concerns with someone not involved in your care, you can contact the Patient Advice and Liaison Service (PALS). This service is confidential and can be contacted on Freephone: 0800 032 0202.

Alternatively, if you wish to make a formal complaint you can contact the patient relations department through any of the details below:

Telephone: 0191 2331382 or 0191 2331454

Email: [nuth.patient.relations@nhs.net](mailto:nuth.patient.relations@nhs.net)

Address: Patients relations department:  
Newcastle upon Tyne Hospitals NHS Foundation Trust.  
The Freeman Hospital,  
Newcastle upon Tyne  
NE7 7DN

**Further information and contact details.**

Please contact Peter Luke by email at [peter.luke@newcastle.ac.uk](mailto:peter.luke@newcastle.ac.uk) or telephone on 07845199255 if you have any queries or questions relating to the study.

If you are interested in participating but English is not your first language, the research team can arrange for the hospital translation service to be on the call when they call to discuss the study further. It is suggested that you record the translated conversation to refer back to in the future.

**Thank you for reading this information.**