PARTICIPANT INFORMATION SHEET

Can left atrial strain measurements, and correlating changes in left atrium area and volume size, be used as an early predictor of atrial fibrillation?

Version number: 4.0 **Date:** 17/05/2023
Site: Withybush General Hospital, Haverfordwest, SA61 2PZ
REC reference: 23/PR/0340
IRAS reference: 324893

Research Study Title: Can left atrial strain measurements, and correlating changes in left atrium area and volume size, be used as an early predictor of atrial fibrillation?

1. Invitation and summary

You are being invited to participate in a research study. Before making any decisions, it is important to explain what the research being conducted is; why it is being conducted and what your role in this study will be. Please take the time to thoroughly and carefully read through this Participant Information Sheet. If you wish, you can also discuss your potential involvement with friends, relatives, and your health care team before deciding. Please do not hesitate to ask any questions, for clarification or for additional information regarding this study.

2. What is the purpose of the research study?

The purpose of this study is to compare subtle changes within the heart between patients with a normal heart rhythm to those with an abnormal heart rhythm called atrial fibrillation (AF). AF is the most common type of abnormal heart rhythm and occurs as the chambers of the heart pump irregularly, often resulting in a fast heart rate and symptoms of irregular pounding and fluttering. Patients that are suspected to have AF are referred for an ultrasound scan of the heart (echocardiogram) which can detect structural changes in the heart's chambers.

Not all AF patients experience symptoms and abnormal rhythms may go undetected, putting patients with untreated AF at an increased risk of stroke.

This study is investigating whether other types of measurements that can be taken during an echocardiogram can detect subtle changes in heart muscle patterns, which can be used as an early predictor of AF. Detecting this abnormal heart rhythm sooner will allow clinicians to better monitor and treat patients and ensure that those at risk receive the correct medications earlier.

The study is being undertaken as part of the Chief Investigator's MSc in Clinical Science course.

3. Why have I been asked to take part?

You have been invited to take part in this research study as you have been referred for an echocardiogram, and are within one of the following categories:

- Normal heart rhythm with normal blood pressure

- Normal heart rhythm with high blood pressure
- Known atrial fibrillation

4. Do I have to take part in this research study?

No, it is completely your decision whether you would like to participate in this research study. This Participant Information Sheet will be provided to you prior to your heart scan for your own information. Prior to your scan, we will aim to contact you via telephone to discuss the research project in detail and answer any questions or queries that you may have. If you would like to take part, you will have been provided with an Informed Consent Form and a Template Informed Consent Form, along with this Participant Information Sheet and Appointment Letter in the post. If all questions have been answered to your satisfaction, and you wish to participate, you can either provide telephone informed consent or written informed consent. If you would like to provide telephone informed consent, this will be done following a discussion of the study prior to your appointment and a member of the research team will go through some questions to ensure that you are happy to participate. The research team will then sign and date the Informed Consent Form and you will either be provided a copy of this whilst attending your heart scan appointment, or in the post following your scan. If you would like to provide written informed consent, please complete the Informed Consent Form provided, following the Template Informed Consent Form. If you are providing written informed consent, you must bring this form with you to your appointment for the research team to also sign. If you forget to bring the form with you, then it may be possible to complete a new one within the department. If we are unable to contact you via telephone before your appointment, we will aim to have a discussion with you during your heart scan appointment. If you would like more time to think about the study following the scan, or we are unable to discuss the study with you during the appointment, we will aim to telephone you following your appointment.

If you decide to participate in this study but wish to withdraw in the future, you are free to do so at any time and do not need to provide a reason for your decision. Unless stated otherwise, we would like to access and keep any medical information collected from you up this point. However, if you choose to withdraw following any processing of your data, it may not be possible to remove your data from the analysis. Please be assured that any decisions you make will not affect your current or future medical care.

5. What will happen to me if I agree to take part in the research study?

If you would like to participate in this research study, you will not be required to attend any additional appointments. You will have a heart scan (echocardiogram) as already requested by a clinician and during and following this scan, additional measurements will be taken by a heart scanner. The additional measurements taken should not extend the duration of your appointment, however, an additional 5-10 minutes may be required to discuss your involvement in the study (if we have not been able to contact you via telephone to discuss the study and your involvement) and to accurately measure your height, weight and blood pressure. These additional measurements will not be included in the echocardiogram report, and instead will be kept separately and used only for the purposes of this research study. Taking part in the research study will not affect or delay the echocardiogram report being received by your clinician (this could be your GP, doctor, nurse or cardiac consultant) and thus, will not affect your current medical care. However, it should be noted that to participate in this study, the image quality must be of a high standard. If image quality is not of the correct standard to be able to accurately trace around the desired heart chamber, then you may be excluded from the study as this may produce inaccurate data. However, you should be reassured that this does not mean your images do not have diagnostic value. The images produced from your scan will still be measured and reported on and sent to your clinician. Additionally, in the highly unlikely event of any incidental findings arising from the additional measurement taken, this

will be dealt with accordingly – as per standard of care. If this were to happen, the results would be reported back to the person that has referred you for a heart scan (echocardiogram) – this may not be your GP. However, your GP will be able to access any tests results using computer systems. Furthermore, if you have any life insurance policies in place, taking part in this study should not affect these policies.

6. What will I have to do?

There are no additional requirements involved in this study on your behalf. A member of the research team will contact you before your appointment to discuss the study and ask whether you are interested in participating and answer any questions or queries that you may have. Verbal telephone consent can be given during this telephone conversation if you wish to participate. Alternatively, if we are unable to contact you prior to your appointment, a member of the research team will discuss the study with you during your appointment and ask you to sign a written consent form. Failing both options, if we cannot contact you prior to or during your appointment, we may ring you following the scan and you can provide verbal consent over the phone. After you have given your consent, you will be assigned a unique participant ID so that any data collected cannot be directly traced back to you. If you choose to participate in this study, the only thing you will need to do is have the echocardiogram, which you have already been referred for. However, some additional measurements will be taken following your scan, but these will not be included in the report of your scan.

7. What are the possible benefits of taking part in the research study?

Taking part in this study will not have any direct benefits to you. However, the results from this research may have wider benefits to the population as patients at risk of developing atrial fibrillation may be more easily identified. This may help with earlier diagnosis and more personalised treatment plans.

Unfortunately, we are unable to pay you to take part in this research study.

8. What are the possible disadvantages and risks of taking part in this research study?

There are no known disadvantages or risks to taking part in this study. There are no known risks associated with echocardiograms. Some pressure is applied to the centre of the chest, on the left ribs, stomach and neck during the scan to obtain images, and this may be uncomfortable for some patients. We will perhaps need an additional 5-10 minutes on top of your appointment time to discuss the research project itself and to obtain accurate height, weight, and blood pressure measurements. All research information (data) will be kept securely, and patient confidentiality will be maintained throughout.

9. What will happen if something goes wrong?

If you have any concerns regarding this study, we encourage you to raise your concerns as soon as possible. You should ask to speak to the researcher who will do their best to answer your questions. Contact details for the researcher are: lucy.hwozdyk@wales.nhs.uk
Contact Telephone Number: 01437 773410

If you wish to speak to someone who is not a part of the study team, you can contact the Community Health Council (CHC):

https://hywelddachc.nhs.wales/

Hywel Dda Community Health Council,

Suite 5,1st Floor,

Ty Myrddin,

Carmarthen, Wales, SA31 1LP.
Phone: 01646 697610

Email: hyweldda@waleschc.org.uk

More details can be found at the hospital if you wanted to take this further and file a complaint. If you feel that you have any reason to complain about any aspect of the way you have been approached in the hospital or further treated during the study, the normal National Health Service complaints mechanisms are available to you.
www.wales.nhs.uk/ourservices/contactus/nhscomplaints

You can also raise a concern by contacting Patient Support Services at Hywel Dda University Health Board by:

Email: **hdhb.patientsupportservices@wales.nhs.uk**
Phone: **0300 0200 159**
Write a letter to FREEPOST FEEDBACK @ HYWEL DDA

10. Will my taking part in this research study be kept confidential?

Yes, all information collected from you during the course of the research study will be kept strictly confidential. Following your appointment, all the information collected about you for the research study will be pseudoanonymised, which involves allocating a unique study ID in the form of a code, or pseudonym. An example of this would be to replace hospital ID numbers with participant numbers (i.e., *Participant 1*) or to include age rather than date of birth. All documents will be password encrypted and kept securely on site. Additionally, no identifiable information will be passed onto any third parties.

How will we use information about you?

We will need to use information from you and from your medical records for this research study.

This information will include your hospital number / name / contact details / date of birth, current medication and previous cardiac history. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep the information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/
- our leaflet on GDPR, provided with this participant information sheet
- by asking one of the research team, or
- by sending an email to chris.tattersall@wales.nhs.uk

11. What will happen with the results generated by this research programme?

The results and findings from this research study may be published in scientific journals and presented at conferences. Please be assured that all results will be fully anonymised and there will be no identifiable information present, thus, it will not be possible to identify you as a participant of this study. You are welcome to email the researcher to ask for updates on this study at lucy.hwozdyk@wales.nhs.uk. If you would like to receive an update on the results of the research study once everything has been completed, we will aim to send this to you. These findings will also form part of a thesis for a MSc course.

12. Who is organising and funding this research?

This research study is being undertaken by the Chief Investigator (Lucy Hwozdyk) as part of a MSc in Clinical Science course at Manchester Metropolitan University. Lucy is also employed by Hywel Dda University Health Board and works within the Cardio-Respiratory department of Withybush General Hospital. The research is being sponsored by Hywel Dda University Health Board. Manchester Metropolitan University will not have any access to any patient identifiable information.

13. Who has reviewed the study?

The research study has undergone review by the Sponsorship Review Group within Hywel Dda University Heath Board, NHS Research Ethics Committee (London - Queen Square Research Ethics Committee) and the British Society of Echocardiography (BSE).

If you require any further information, please do not hesitate to contact:

Lucy Hwozdyk
Email: lucy.hwozdyk@wales.nhs.uk
Contact Telephone Number: 01437 773410
Trainee Clinical Scientist – Cardiology
Withybush General Hospital
Hywel Dda University Health Board

INFORMED CONSENT FORM

Version 4.0 **Date: 17/05/2023**

Research Study Title: Can left atrial strain measurements, and correlating changes in left atrium area and volume size, be used as an early predictor of atrial fibrillation?

Participant identification number:

Site: Withybush General Hospital, Haverfordwest, SA61 2PZ

Research Team Lead: Lucy Hwozdyk lucy.hwozdyk@wales.nhs.uk

Contact Telephone Number: 01437 773410

Read the following statements carefully. If you agree to these statements, please write your INITIALS (do not tick) in the adjacent boxes.

		INITIAL BOX
1.	I confirm that I have read and understood the Participant Information Sheet (Version 4.0, dated 17/05/2023) for the above research study. I have had the opportunity to ask questions, and I am happy with the answers given.	
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3.	If relevant, I understand that sections of any of my medical notes may be looked at by responsible individuals from the Research Team or regulatory authorities where it is relevant to my taking part in research and the sponsor's representatives in Hywel Dda University Health Board for monitoring the conduct of the study. I give permission for these individuals to have access to my records.	
4.	I confirm that I have understood all the information above, and I agree to take part in the research study: *'Can left atrial strain measurements, and correlating changes in left atrium area and volume size, be used as an early predictor of atrial fibrillation?'.*	
5.	I confirm that I am happy for the research team to contact my General Practitioner (GP) in the event of any incidental findings that may arise as a result of participation in this study.	
6.	I confirm that I am happy to be contacted for any future research that may be required following this research study.	

Full Name of Participant (PRINT)	***Date:**	***Signature:**
Full Name of Person receiving consent (PRINT)	**Date:**	**Signature:**

Research Team only:

☐ *Tick if written consent has been obtained.*

☐ *Tick if telephone consent has been obtained.*

**if telephone informed consent has been obtained, participant date and signature boxes do not need to be inputted.*