PATIENT INFORMATION SHEET

Full study title: Inflammation and Salt-Inducible Kinases – A Potential Novel Therapeutic Strategy in Patients with Heart Failure

Chief Investigator: Dr Ify Mordi, Clinical Senior Lecturer and Honorary Consultant Cardiologist

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We would like to invite you to take part in a research project. However, before you decide whether you wish to participate, we need to be sure that you understand firstly why the research is being done and what it involves for you. One of our team will go through the information sheet with you and answer any questions you have. Please take as long as you need to read and understand this patient information sheet, and if you wish, discuss it further with friends or family. Please feel free to ask any questions you wish. We will do our best to explain to provide any further information you may ask for now or later. You do not have to make an immediate decision.

If you decide that you would like to take part in this study, then please return the attached reply slip (in-person, by post or email) so that we can meet with you to discuss the study and answer any questions that you have. If you are happy to be involved we will ask you to complete a consent form.

Why are we doing this research?

We would like to invite you to participate in this study of patients like you that either have heart failure (HF) or have heart muscle changes that can sometimes lead to HF. Although medical advances have led to improvements in treatments for some types of heart failure, there are still many things we can improve to help patients live longer, prevent hospital admissions, and improve quality of life. Previous studies have suggested that high levels of inflammation might either cause HF or lead to worse symptoms in patients with HF. Levels of inflammation in the bloodstream are regulated by a number of different substances. One of these is a group of substances called salt-inducible kinases (SIKs). In this study, we are going to find out whether levels of SIK activity are related to heart muscle structure and function and symptoms of HF.

If we can understand relationship between SIK activity and inflammation in HF, we could potentially develop new, much needed treatments to improve patients' lives.

We plan to recruit 100 HF patients. We will collect detailed clinical information and blood samples from patients who have consented to participate. This type of study is particularly important as we plan to study a variety of patients with HF, rather than limiting to certain groups, to get a "real-world" picture of how heart failure affects patients.

Why have I been contacted?

We are inviting you to ask if you would consent to participate in our research project as you have been diagnosed with heart failure or have heart changes on your echo scan that can sometimes lead to heart failure.

What would I have to do?

To help us with our research, we would require you to:

- Provide a blood sample (of approximately 50mls, or 5 tablespoons). This will be taken by a member of the research team.
- Allow us to perform a heart scan (echocardiogram, an ultrasound test). You may have had one performed before as part of your clinical care – if you have had a detailed scan within the previous 6 months you will not need another one. We will put some stickers and some cold jelly on your chest before we take pictures by placing a probe on your chest. The test lasts around 30 minutes.
- Complete a questionnaire about how your life is impacted by heart failure.
- Allow us to record your past medical history and blood results.
- Allow us to follow up your clinical care by review of relevant medical records.

We will perform these tests at your first visit. If you are currently in hospital, we will perform 2 blood tests while you are in, one within 48 hours of your admission and one at 5 days (or prior to discharge if you are discharged before 5 days).

Depending on the level of inflammation you have on the first blood test we may ask you to come back for another blood test in 6 months. We will contact you at the time to ensure you are happy to do this. We plan to do this in around 40 patients. The study will be complete 6 months after the final participant selected has had their 6-month visit – at that stage your participation will be complete.

All tests will either be performed in the cardiology ward or the Division of Molecular and Clinical Medicine, Ninewells Hospital.

Would there be any risks?

The standard technique for taking blood would be used and if you have given blood before, you will know that you may experience some brief discomfort and/or bruising at the site. You may well also have had an echo scan before. It can sometimes be a little uncomfortable as we occasionally need to press on your chest with the probe to get good pictures, but generally patients also manage this without any problems.

It is unlikely that we will identify any findings that will affect your current clinical care, however, if we do, with your consent, we will let your cardiologist and/or GP know.

Precautions against COVID-19 will be taken according to current local/national guidance, such as mask-wearing and social distancing.

If at any point you have concerns, as well as discussing with the research team you can also discuss them with your cardiologist or GP.

Could I choose not to take part or withdraw from the study?

Yes, participation in this study is entirely voluntary and you are free to refuse to participate or withdraw from the study at any time (without having to give a reason) and without this in any way affecting your future medical care or your relationship with medical staff looking after you. If you wish to withdraw, you simply need to inform a member of the research team. With your permission, any data collected prior to withdrawal will be stored anonymously for analysis purposes. Contact details for the research team can be found on the last page of this information sheet.

What are the possible benefits of taking part in the study?

We already know that heart failure is a major public health issue worldwide. There may not be any direct benefits to you immediately from taking part in the study, however the information we obtain will be useful for us to understand the problems patients with heart failure have. In future we any study findings we make might be useful in understanding why heart failure develops and in developing new treatments for heart failure. These results will be of interest to those involved in providing healthcare and may influence the way we use existing treatments and the advice we give. If we do identify something that may impact on your clinical care we will tell you and your clinician immediately. We will also cover reasonable travel expenses. If you are interested we will send you a summary of the full study results by email or post – please let us know at any point.

What about future research?

Some of the information and blood samples we collect may be stored and used for future research. After the study there may be some extra blood that we wish to store for future research. This will be stored in the Division of Molecular and Clinical Medicine and registered with the Tayside Biorepository. This research will always use anonymous information.

Who has sponsored and organized this study?

This study has been sponsored by the University of Dundee and organized by Dr Ify Mordi. The study is funded by the charity Tenovus.

Who has reviewed this study?

This study has been reviewed and approved by [name of REC] who are responsible for reviewing research which is conducted in humans. The Research Ethics committee does not have any objections to this study going ahead.

Will my taking part in the study be kept confidential?

It is a requirement that your records in this research, together, with any relevant medical records, be made available for examination by regulatory authorities, monitors from the study Sponsor, the University of Dundee.

Information we collect about you and your healthcare records, and the results we obtain will remain strictly confidential. All information will be held on a secure database that will be accessible only to staff directly involved in the project. Your personal details (name, address, date of birth, etc.) will be held separately from the other information collected. Your details will not be given to any third party, nor will it appear in any report or publication that arises from this study.

Insurance

The University of Dundee is sponsoring the study. The University of Dundee has a policy of public liability insurance which provides legal liability to cover damages, costs and expenses of claims.

What if something goes wrong?
If you are concerned about your participation in the study you have the right to discuss your concern with a researcher involved in the study or a doctor involved in your care.
If you have a complaint about your participation first of all please talk to the researcher.
If you are not satisfied, you can make a formal complaint to a senior member of the research team or to the Complaints Officer for NHS Tayside.

Complaints and Feedback Team
Ninewells Hospital Dundee DD1 9SY
Freephone: 0800 027 5507
Email: TAY.feedback@nhs.scot

If you think you have come to harm due to taking part in the study there are not any automatic arrangements to get financial compensation. You might have the right to make a claim for compensation. If you wish to make a claim, you should think about getting independent legal advice but you might have to pay for your legal costs.

How will we use information about you?

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

This information will include your NHS number/name/ contact details, which will be held by the research team. 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 some of 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 information about you that we already have.
- **OPTION if follow up data will be collected after withdrawal:** If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records. If you do not want this to happen, tell us and we will stop.
- 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.
- **OPTION if data will be used for future research:** 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 including blood samples stored in the Tayside Biorepository.

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

You can find out more about how we use your information from the study team.

Who should I talk to if I have any questions or concerns?

If you have any questions regarding this study, you can write or telephone at the addresses shown below:

Dr Ify Mordi
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DD1 9SY
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Dr Adel Dihoum
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Thank you for considering our request to take part in this research.