NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

UNIVERSITY OF OXFORD

Patient Information Sheet

Feasibility study of the use of point-of-care NP measurement in primary care in patients with heart failure

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IRAS reference: 234119 Ethics reference: 17/NI/0229

Chief Investigator: Professor Rafael Perera

You are being invited to take part in a research study looking at a quick blood test to monitor heart failure. This information sheet explains why the research is being carried out and what will be involved if you choose to take part. Please read it carefully and talk to others about the study if you wish.

Please contact the research team if anything is not clear, or if you would like more information. Their contact details are at the end of this information sheet.

What is the purpose of the study?

Heart failure is a condition where the heart does not pump blood around the body as well as it should. Although it is called heart "failure", the heart is still working, but may be under some stress. This can cause a change in the level of natriuretic peptide (NP) – a marker in the blood which can be measured by doing a blood test. NP testing is used to help diagnose heart failure, and there is some research that shows that monitoring NP may also be useful to help guide treatment in people who already have the condition. It is possible for a doctor or nurse to measure NP from a blood sample themselves with a small portable machine (a "point of care" test), instead of sending it to a laboratory. This means that they get the result quickly, which may be useful to allow them to make an immediate decision about whether to change a patient's treatment, or to send them to hospital. We want to see if it's practical for a GP or nurse to use this quick blood test to monitor their patients.

Why have I been invited?

You have been invited because you are over 18 years old, and you have been diagnosed with heart failure in the past.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do take part, you will be given this information sheet to keep and be asked to sign a consent form to say that you understand what the study involves. You are free to withdraw at any time, without giving a reason. A decision to withdraw or a decision not to take part will not affect the standard of care that you receive.

If you become unable to make decisions for yourself during the study, we will withdraw you from the study at that point. We will still be able to use the research information collected with your consent up to the time when you are withdrawn.

What will happen to me if I take part?

All the appointments will take place at your own surgery, or at home if you normally receive home visits. They will be carried out by a nurse or GP.

At the first appointment, the nurse or GP will explain the study to you, and give you time to read this information sheet and the opportunity to ask any questions about the study you may have. If you decide you would like to take part in the study we will ask you to sign a consent form. The nurse or GP will explain about the follow up appointments which will be 6 months and 12 months after the first appointment.

The first appointment

This will take approximately 45 minutes during which:

- We will collect some information about you, including your age, gender and ethnicity, which will help us to interpret the results of your blood tests.
- We will measure your weight, blood pressure, and pulse, and check your heart rhythm.
- We will ask about your medical history and any medications you are taking.
- We will take blood tests to measure NP using the quick test, a slower test at the laboratory, and tests of how well your kidneys are working. In total, we will take about 21ml of blood (about 3-4 teaspoons.)
- We will ask about how your heart failure affects you, and help you to complete a questionnaire about this.

Appointment after 6 months

This will take approximately 20-30 minutes during which:

- We will measure your weight, blood pressure, and pulse, and check your heart rhythm.
- We will ask about any changes in your medical history and any medications you are taking.
- We will take blood tests to measure NP using the quick test, a slower test at the laboratory, and tests of how well your kidneys are working. In total, we will take about 21ml of blood (about 3-4 teaspoons.)
- We will ask about how your heart failure affects you, and help you to complete a questionnaire about this.

Appointment after 12 months

This will take approximately 20-30 minutes during which:

- We will measure your weight, blood pressure, and pulse, and check your heart rhythm.
- We will ask about any changes in your medical history and any medications you are taking.
- We will take blood tests to measure NP using the quick test, a slower test at the laboratory, and tests of how well your kidneys are working. In total, we will take about 21ml of blood (about 3-4 teaspoons.)
- We will ask about how your heart failure affects you, and help you to complete a questionnaire about this.
- We will ask you to rate how acceptable you thought the quick blood test was.
- We may invite you to take part in a focus group to discuss your opinions about the study, either at

this appointment or soon afterwards. It will be up to you whether or not to take part in the focus group, and we will provide extra information to help you make this decision.

- After this appointment, your GP notes will be reviewed. We will record when you visited your GP surgery during the year, and the reason for these visits, as well as any times you were admitted to hospital during the year, and the reasons for those admissions. The review will be carried out by someone employed by the GP surgery. The research team will not have access to your medical notes.

Other appointments

Between the first appointment and the last study appointments, if you see someone from your GP surgery about your heart failure, we will ask them to record some extra information to help with the research. A lot of these are things that they would do anyway to look after you, such as measuring your weight, blood pressure and pulse, checking your heart rhythm, and checking to see if there have been any changes in your medical history or medication. However, we will also ask them to do two blood tests. One of these will be the quick NP test, and the other will be to see how well your kidneys are working. For this, they will take about 12ml of blood (about 2-3 teaspoons). If it is not practical to do the tests, or if doing the tests would delay your treatment, they won't do them. Doing these extra blood tests might add about 15 minutes to your appointment time (possibly a bit longer if you have to wait for someone to take your blood.) You can choose not to have the extra blood tests done if waiting to have the blood taken would be inconvenient for you.

Expenses

We are unable to pay you for taking part in this study; however we can reimburse reasonable travel expenses that you may incur for the extra study appointments.

What are the possible benefits of taking part?

It is important to note that you may not benefit personally from taking part, but that the results of the study may help in improving future care for patients with heart failure. However, you will have some extra blood tests carried out as part of the study. Your doctor will have access to the results of these tests, and may choose to use the results to help with managing your treatment.

What are the possible disadvantages of taking part?

The study will require you to attend extra appointments at the surgery for the study information to be collected, and your other appointments for heart failure may be longer than usual. You may need to have more blood tests than usual. Some people experience pain or bruising after having a blood test, although we will aim to minimise this.

What happens when the research study stops?

Once the study ends, your GP will continue to look after you and review your treatment as necessary.

What if there is a problem or anything goes wrong?

The University has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research (Newline Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Prof Rafael Perera on 01865 289308 or rafael.perera@phc.ox.ac.uk, or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG, email ctrg@admin.ox.ac.uk

Will my taking part in this study be kept confidential?

Yes. We will follow standard ethical and legal practice and all information about you will be handled in confidence. The study information will only be seen by the Research Team and will be stored in accordance with the Data Protection Act at the University of Oxford. The study data may also be looked at by representatives of sponsor organisation or regulatory authorities to check that the study is being carried out according to the protocol.

In the future, we may share your anonymised research data with other researchers, including researchers based outside the EU. This could help with future research into heart failure or other health conditions. If we share the research data in this way, we will make sure that you cannot be identified from the shared data.

What will happen if I don't want to carry on with the study?

You are free to withdraw at any time and this will not affect the standard of care you receive. Information collected earlier in the study may still be used unless you do not wish us to use it.

What will happen to any samples I give?

Your blood samples will be destroyed after being analysed.

What will happen to the results of the research study?

The results of the study will help to inform future studies about monitoring people with heart failure. The results will also be written up and published in health professional journals and may be presented at conferences in the UK and abroad. If you wish to know the results of the study then we will make copies available.

Who is organising and funding the research?

The University of Oxford, Nuffield Department of Primary Care Health Sciences are co-ordinating the study. Funding is provided by the National Institute for Health Research's (NIHR) Programme Grants for Applied Research (PGfAR) Programme

Who has reviewed the study?

Before deciding whether to fund the study, the National Institute for Health Research asked the opinion of several independent experts. The study has also been reviewed and approved by the HSC REC B ethics committee (reference 17/NI/0229).

Thank you for taking time to consider participating in this study. If you have any concerns or questions about the study, please contact the study manager using the details below:

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