

### What if I don't want to take part in this study?

Participation in this study is voluntary. It is completely your decision whether you participate. You can also withdraw at any point during the study. If you wish to withdraw after the study you can do so. Although any anonymised data cannot be withdrawn.

### What happens with the results?

Results may be published in peer-reviewed journals and an academic thesis. All data will be anonymised before publication so no one will be able to identify you.

### How will my confidentiality be protected?

You will be assigned a study number that will be used to identify you. Your data will be anonymised at the time of collection and saved using your study number. No identifiable information will be used when we store your results from the tests. Contact details and consent forms will be saved in paper form securely in a locked cupboard at Liverpool John Moores University. Contact details will only be used to notify participant of abnormal blood cholesterol levels. The participant identifiable information will be destroyed after 6 months. Study data (anonymised scans, blood pressure, heart rate and blood cholesterol levels) will be stored on secure Liverpool John Moores University network and destroyed after 5 years (Dept of health guidelines)

If your test results are found to be abnormal, your study number will be used to retrieve your name and contact details from your healthcare questionnaire. You will then be contacted and notified. You will be asked to seek advice from your GP.

### What should I do if I want to discuss this study further?

If you have any questions please contact the Chief Investigator, Arron Peace at

A.T.Peace@2016.ljmu.ac.uk

Tel: (0151) 231 4666

### What if I have any concerns about the study

If you have any concerns about how the study is being conducted you can contact Liverpool John Moores University sponsor Dr David Harriss at D.Harriss@ljmu.ac.uk



## Participant Information Sheet

### Effect of Blood Pressure on Arterial Function and Cardiac Risk

You are invited to participate in a research study to investigate the effects of Blood Pressure on risk of Cardiovascular Disease in healthy men.

Before you decide if you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.

## Background

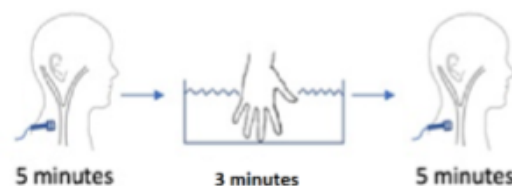
Hypertension is an important and common risk factor for Cardiovascular disease. The risk of having a heart attack or stroke can be predicted by how easily the coronary arteries are able to expand. This ability to expand is reduced in severe hypertension. The ability of the coronary arteries to expand is difficult to assess due to their positioning. It has been demonstrated that the carotid arteries, that run either side of the neck, can be used as a proxy measure for the coronary arteries. They can be measured using non-invasive ultrasound, a method currently used in clinical practice when investigating the health of the carotid arteries. To cause the arteries to expand, the participants hand will be submerged in icy-cold water for 3 minutes. The change in the diameter of the carotid artery will be measured throughout. The ability of the arteries to expand and contract will be measured in individuals with normal and a slightly raised Blood Pressure. This will also be compared to measured used in the hospital to predict risk of cardiovascular disease

## What does the study involve?

You will be asked to attend Liverpool John Moores University. The project will be explained to you and you will have an opportunity to ask any questions. If you wish to participate you will be asked to undertake a health questionnaire.

The large arteries of the neck (carotid arteries) will be scanned using an ultrasound machine. This is a non-invasive technique meaning we will not break the skin or have you take any medications. It is routinely used in the hospital to predict the risk of stroke.

There should be no pain but you may feel pressure on the neck. Your hand will then be submerged in icy-cold water for 3 minutes and the carotid arteries scanned throughout. This may cause mild to moderate discomfort. You can stop the test at any time. The whole process will take 15 minutes. Your blood pressure and heart rate will be measured non-invasively throughout using a cuff on the arm and



A small amount of blood (5ml) will be taken from a vein in the arm. This will be used to measure the amount of cholesterol in your blood. This will be used together with your blood pressure, heart rate and health questionnaire to calculate your QRISK3 score. This is used in the hospital to predict your risk of having a heart attack or stroke. Your blood pressure and measures of artery health will be compared to ability of the arteries to dilate to investigate if raised blood pressure is as a result of an inability of your arteries to dilate. This will also be compared to your QRISK3 score to investigate if ability to dilate is predictive of cardiovascular disease.

## Am I eligible to take part?

We are looking for healthy men who are aged 30-60 with no history of cardiovascular disease and not currently taking medication for cardiovascular disease or disease/damage to the hand used during testing or a history of seizures/fainting.

You must avoid exercise, smoking, food or drink the night before you are coming in for the study. Studies are therefore undertaken in the morning. Although this can be changed to accommodate you.

## Will I benefit from the study?

If any abnormalities are found during carotid artery ultrasound, blood cholesterol, blood pressure, heart rate or measures of artery health are found to be abnormal, you will be advised to seek advice from your GP. If your blood cholesterol levels are high you will be contacted using the contact details you provide during the health questionnaire.

A long-term benefit of the trial is that participants will contribute to the development of medical understanding. This may, in the future be used to improve clinical decision making.

## Are there risks to me in taking part in this study?

The most common risk associated with the Cold Pressor Test is moderate discomfort associated with submersion of the hand in cold water. You are free to remove your hand from the water at any time. The hand will only be submersed in cold water for precisely 3 minutes. There is also a slight risk of the Cold Pressor Test causing mild angina chest pain. In the unlikely event that you experience any chest pain, your hand will be removed from the water. The chest pain will likely resolve itself.

There are also some risks associated with collection of blood from a vein. There is a very small risk of infection associated with inserting a needle into a vein. There are also risks associated with puncturing an artery, rather than a vein. These potential risks are avoided with the training undertaken at Liverpool John Moores University and adhering to strict guidelines.