University Hospitals Bristol NHS
NHS Foundation Trust

University of BRISTOL

MRC Medical Research Council

Participant Information Sheet

Title of study: Understanding the link between gum disease and heart attacks

We would like to invite you to take part in our research study. Before you decide, 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 and decide whether or not you wish to take part. Please ask us if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

Heart attacks are the main cause of premature death in the UK. It is important to carry out research in this area in order to improve both the health and life expectancy for those at risk of heart disease.

It is well known that inflammation within the blood vessels that supply the heart can lead to heart attacks. Inflammation occurs when specific cells within our blood, known as monocytes, respond to a signal and start to invade the cells lining the blood vessels. It is also known that individuals with gum disease (periodontitis) may be at greater risk of suffering a heart attack. However, this link is not fully understood and so further research is required.

We have evidence from laboratory studies that gum disease may cause changes in monocytes that can lead to inflammation. This could help to explain why gum disease may promote the onset of heart attacks. We now need to confirm these findings. This study therefore aims to demonstrate that monocytes taken from patients with gum disease behave differently to those taken from healthy (good gum health) volunteers. A greater understanding of these processes may ultimately enable the design of improved therapeutic treatments for heart attacks.

Why have I been invited to take part?

You have been invited as you are attending the Dental Hospital for an appointment. We are hoping to recruit 270 people to take part in the study. This will made up of people attending the Dental Hospital for appointments.

Do I have to take part?

No, it is up to you to decide if you want to join the study. We will describe the study and go through this Information Sheet with you. If you agree to take part, we will then ask you to sign a Consent Form. You are free to withdraw at any time, without giving a reason. This will not affect your dental treatment in any way. If you do decide to withdraw from the study then any samples or data collected up until the point you withdraw will be kept and used.

What will happen to me if I decide to take part? What will I have to do?

If you decide to take part, your dentist or a member of his/her clinical team will take blood from your arm and assess your gum health. Some people will also be asked to provide a small sample of saliva (every 5th person will be asked to do this). The whole process should take no more than 20 minutes:

1) The clinician will perform a basic periodontal examination to give your gum health a score. This score will allow the clinician to decide if you meet the criteria to be included in the study.
2) The blood sample will be taken by a dental practitioner in the dental chair of the clinic. It is like any other blood test you may have had before. A band will be placed around your upper arm and a needle inserted into a vein in your arm to take enough blood to fill two tubes, each about the same size as the index finger on a small adult hand (about 20 ml in total). Initially you will feel a sharp pricking sensation, but only briefly. Once the blood has been taken, pressure and a covering will be applied to the site.
3) A sample of your saliva will be collected. You will be asked to rinse your mouth with tap water and then gently spit into a sterile tube (about 2 ml in total).

4) Some people who go on to have treatment for their gum disease at the Dental Hospital will be asked to provide additional blood and saliva samples during and after their treatment.

There will be no change to the routine dental treatment that you have attended the hospital for. This will be carried out as normal.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your date of birth, gender, and your gum health score. 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. 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/
- by asking one of the research team
- by sending an email to the Chief Investigator Dr Dáire Shanahan ds17344@bristol.ac.uk ,
- by ringing us on 0117 34 29641 or
- by contacting the University of Bristol Data Protection Officer by sending an email to data-protection@bristol.ac.uk or ringing 0117 39 41824

What will happen to my samples and my score?

All samples will be stored using a unique number (a code) which can only be traced to you via a secure database with restricted access.

Only the clinical staff will know who the samples and scores come from. The samples will then be collected by the researcher. Monocytes will be isolated from the blood sample. The inflammatory behaviour of these monocytes will then be determined using several standard experiments in the laboratory. The saliva will be tested for the presence of certain proteins that may be associated with inflammation. Unused samples may be used in another ethically approved research project at the University of Bristol or at other universities. If this occurs your information will remain safe and secure. This means that any information we collect about you is separate from your personal details, and we can only link this information together with a secure code. Only authorised members of the research team will have access to the information.

Who will have access to my samples?

Only the clinical staff who took the samples and the researchers carrying out the laboratory experiments will have access to the samples.

What are the possible disadvantages of taking part?

When blood is taken there will be a sharp scratch from the needle but this should not last long. A slight discomfort and bruising may be

experienced due to withdrawal of blood, but this is no different to giving blood for a blood test.

What are the possible benefits of taking part?

We cannot promise the study will help you, but the information we get from this study will help to further understanding of the link between gum disease and heart attacks, and may enable improved treatment of people at risk of heart attack.

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

You can withdraw from the study at any time without giving a reason. This will not affect the dental care that you receive now or in the future.

If you do decide to withdraw from the study any samples or data collected up until the point you withdraw will be kept, used and included in the analysis.

What will happen to the results of the study?

The researchers involved with the project hope to report the data in research journals or at professional meetings, but as the samples are anonymised, your identity will not be revealed. If you would like a summary of the results you can contact the researchers using the contact details at the end of this Information Sheet.

At the end of the study, the results will be made available as "open data" on the data.bris Research Data Repository. This means the results can then be used to support other research in the future, and may be shared anonymously with other researchers. However, as the samples are anonymised, it will not be possible to identify you from this information.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do their best to answer your questions. Alternatively, you could speak to the Chief Investigator, Dr Dáire Shanahan(email: ds17344@bristol.ac.uk, telephone: 0117 34 29641). If

you remain unhappy and wish to complain formally, the normal NHS complaints process is available to you. In the unlikely event that you are harmed by taking part due to someone's negligence, then you may be able to take legal action.

Who is organising and funding the research?
The Medical Research Council is funding this study at the Bristol Heart Institute, University of Bristol.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics committee to protect your safety, rights, wellbeing and dignity. The research was assessed and supported by the Medical Research Council.

About the consent form
If you are happy for us to collect and use a sample of blood and saliva for research we would like you to confirm that you have given us your consent (permission) by completing the Consent Form on the last page. Please note that you do not have to give your consent. If you do not wish to give your consent it will not affect the quality of care you will receive in any way.

All consent forms are kept in a secure location with restricted access. Consent forms are kept until the samples are used or on rare occasions when the samples need to be destroyed. Confidential NHS waste processes will be used to destroy the consent forms.

For more information regarding the project contact Dr Dáire Shanahan, Bristol Royal Infirmary Level 7, Upper Maudlin Street, Bristol BS2 8HW; Email: ds17344@bristol.ac.uk