

INFORMATION LEAFLET

You are being invited to take part in a research study. Before you decide whether to take part 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 discuss it with others if you wish. Please contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you.

What is the purpose of the study? We are trying to find out more about the causes of gastric (stomach) cancer, so that we can find ways to prevent it. Some people with gastric cancer have a family history of the disease, and those cases might be related to inheriting certain genes, which are made up of DNA. We would like to be able to identify these genes in order to understand the disease better. We hope that by studying the genes involved we can help local genetic centres to give accurate advice to families with a history of stomach cancer in the future.

We are also trying to find out more about the causes of stomach (gastric) and oesophageal (gullet) cancer in individuals diagnosed with the disease under the age of 50, so that we can help find better ways to treat them. One way to study genes that may be involved is to compare blood samples from patients with the disease.

Who will benefit from the research? This research may benefit individuals and families with a history of stomach cancer should new genes be identified which make people more susceptible to stomach cancer. It may also help to improve treatment and information given to patients with the stomach or oesophageal cancer in the future.

Why have I been chosen to take part? You have been chosen because you have a family history of two or more relatives with stomach cancer or you have been diagnosed with stomach or oesophageal cancer yourself under the age of 40 years.

What would I have to do? We will ask you for details of your family history and medical history. This can be done by the research nurse on the phone or by post if you prefer. If you have attended a genetic centre for advice about your family history we can contact them for the information. We may need to obtain your medical and pathology reports from relevant hospitals. We may also need to contact cancer registries and pathology departments using the information you give us, to help confirm the diagnosis of cancer in your deceased relatives. The release of this information to us is supported by the Patient Information Advisory Group (PIAG). This information will not be released to you but will be used by the research staff to assess what testing may be appropriate for your blood samples.

We will ask you for a blood sample (20mls or 4 teaspoons) – just like the one which is taken for ordinary blood tests. This can be taken by your GP, or if this is not possible we can make other arrangements. This will be used to look at the role of genes which may increase the risk of stomach cancer, and to look at how blood cells grow and develop. We will send all the necessary equipment to you by post so you can have the blood sample taken and it will have adequate postage and be addressed appropriately for safe return to our laboratory in Cambridge. Alternatively, you may opt to provide us with a sample of your saliva, in which case we will send you the pot and packaging for return to Cambridge.

We may ask you to contact some of your relatives, and ask whether they would be willing to help us with our research. If they agree we would ask you to pass on information sheets to them about the study and consent forms to sign. At no time will any of your personal or medical details be passed on to them.

We will ask you to give permission for the research team to access pathology samples from yourself (if you have had an operation or biopsies taken in the past) or deceased members of your family who had cancer. These are routinely stored in the pathology department of the hospital at the time of operation.

Your GP or hospital consultant may feel it is necessary for you to have an endoscopy examination of your stomach. This endoscopy would be part of your routine care anyway. We would be able to offer this as part of the study. It is a research procedure which we are trying to improve and develop. It is as yet unproven as being effective in detecting early gastric cancers. However, with the information gained from the endoscopies carried out in the study we hope to analyse how effective it is and develop and improve the procedure offered to individuals at risk in the future. This endoscopy could be carried out in Cambridge or London but could also be done at your local hospital, under guidance from Cambridge, if you prefer not to travel. (It would not however be possible to reimburse travel expenses to Cambridge or London). It is estimated that it may take approximately 20 minutes, and require taking 30 samples. These biopsies would be used to examine the changes in the cells lining your stomach. The biopsies would be analysed by a hospital pathologist and the results would be used to help decide on your medical care. This would be part of your clinical care and reported to the hospital doctor who requested your endoscopy. We would also like to store the biopsies viewed by the pathologist and some additional frozen biopsies for use in research relating to stomach cancer as new strategies develop. We would also like your permission to obtain tissue from any biopsies you may have had taken in the past which may be stored at your hospital pathology department.

Who will know my personal information? We will not pass on any research information to anyone, not even other members of your family, or your GP, without your permission. We will, with your consent, contact your GP and the hospital consultant in charge of your care, simply to inform him that you are taking part in the study. All the information you give us will be completely confidential in accordance with the Data Protection Act 1998. Authorised staff from a research and development audit office may have access to our information in order to assess that we are working to research guidelines.

How will my samples and data be stored? The blood sample will be sent to Strangeways Research Laboratory in Cambridge (part of the Addenbrookes Hospital campus) where it will be stored for as long as the study has ethical approval. It will be given a numerical identification number. All information you give us will be stored on a secure database and in a locked filing cabinet in the department of Oncology in Addenbrookes Hospital in Cambridge. Only members of the research team working with your information, namely the research nurse, research assistant and lead investigator will know your identity. No laboratory staff doing analysis on your sample will know your identity. The pathology samples will also be given a numerical identification. They will only be used to study aspects of stomach or oesophageal cancer as new research strategies develop. Every change to the study regarding the use of these samples will be subject to approval by an ethics committee.

Will there be any results from the samples? When you give your blood sample, we will provide you with a form where you can indicate whether or not you would like to be informed if we find something that may be relevant to your family.

Any findings received from the examination of your blood sample and pathology samples which may be relevant to the clinical care of you and your family will be relayed to you by the geneticist looking after you. Also information regarding diagnosis of cancers in your deceased relatives can, with your consent, be given to the genetic centre involved.

What happens if anything goes wrong? Side effects of giving a blood sample are uncommon and mostly minor, such as bruising or tenderness. The research team is insured (indemnified) should you come to any harm as a result of negligence. If you have a problem or complaint you can contact Sue Richardson (see below). You could also pursue the matter through the NHS complaints procedure in exactly the same way as you would be able to if you were receiving standard NHS treatment and were not participating in a research study.

If I have any questions who can I ask? Sue Richardson the Research Nurse will be pleased to answer any queries you may have. She can be contacted by telephone on 01223 330019. Or you can write to her at the above address.

What if I would rather not take part? There is no pressure on you to take part, if you would rather not. Also, you can change your mind and leave the study at any time. You don't have to give a reason. Your decision will not affect your own care or treatment in the future, or that of anyone in your family. If you should choose to withdraw from the study you can choose to have your blood samples, tissue samples and all information you have given us destroyed.

What happens to the results of the study? The results from the analysis will be discussed at scientific meetings and published in medical peer review journals. Individuals will not be identified in any report or publication. In the long term any discoveries from this research will be used to improve the treatment and advice given to patients.

Who is doing the Research? The study is being carried out by a team from The University of Cambridge headed by Professor Carlos Caldas and is funded by Cancer Research UK. The research staff are not being paid for your participation.

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