



## Information for patients

<b>Study title</b>	<b>Screening for carbon monoxide in emergency departments</b>
<b>Leaflet version</b>	v1.6 01 October 2018

You are being invited to take part in a research study. You may have already told us that you are happy to take part. We do this so that your treatment is not delayed. To include you in the study, we also need your permission in writing. Before you decide, it is important for you to understand why the research is being done and what it involves. Please take time to read this information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

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### **What is the purpose of this study?**

Carbon monoxide poisoning can cause a variety of symptoms that may be mistaken for other conditions; if the diagnosis is missed it may lead to long-term disability or even death. Unfortunately, no-one knows exactly how big a problem this may be. At the moment we can do a test in the Emergency Department for carbon monoxide in the blood but it may not be very accurate and it is possible that we do not detect carbon monoxide in some patients.

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### **Why have I been invited to take part in this study?**

We are looking to invite patients to join the study if they come to the Emergency Department with one of the following symptoms:

- Chest pain
- Dizziness and faints
- Fits
- Flu-like symptoms
- Headaches that have not been caused by an injury

These symptoms may result from exposure to carbon monoxide.

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### **What will happen to me in the study?**

If you take part in this study you will still receive exactly the same treatment. Your treatment will not be delayed or changed if you decide to take part. You may have already told us you are happy to take part and have had a blood test by the time you read this information. As part of your clinical care we will measure the carbon monoxide levels in that blood sample. Two extra blood bottles taken for research purposes will be sent to a laboratory where they will measure cotinine levels (an indicator of smoking tobacco, an activity which also increases the levels of carbon monoxide in your blood) and look for other evidence of carbon monoxide exposure. The small volume of blood drawn for research purposes (approximately 8 - 10ml or two teaspoons) will not cause any harm. Sometimes we



can take the blood sample from an intravenous cannula (a plastic tube that sits in the vein) without having to use another needle. You will be asked to complete questions on your health and about possible sources of carbon monoxide, such as your heating system at home or work. This will take no more than 10 minutes. You can do this while waiting for the doctor who will be looking after you.

*If the doctor suspects you may have been exposed to carbon monoxide* (if the levels of carbon monoxide in your blood are higher than expected), your doctor will discuss this with you. In this case, a referral to a qualified emergency gas engineer from the National Gas Emergency Service will be made. They will visit the place that may be causing suspected exposure to check for higher than normal levels of carbon monoxide; this could be your home or workplace. They would do this for any person with suspected carbon monoxide exposure even if they were not in the study. They do this to make sure that you or anyone else is not at further risk and to make any immediate issues safe. With your permission they will carry out checks, including testing fossil fuel-burning appliances to see if they are producing carbon monoxide. It is possible for some of these checks to take place even if they are not able to enter the home or workplace. Please note, this assessment is free *but the research project does not fund replacement appliances such as faulty boilers*. The emergency gas engineers will give you further advice if required. You will also be referred to the local public health team for follow up. We would do this for any person we thought may have been exposed to carbon monoxide.

If you agree to taking part in this study, we will have all that we need for our research and will not need to contact you again. Blood samples will be treated as gifts to research and held at Public Health England (PHE), in accordance with Human Tissue Authority regulation, until the research has been completed.

If you do not wish to participate we will not collect the extra sample bottles and your carbon monoxide level will not be recorded as part of the study. If these samples have already been collected they will be discarded. If the doctor treating you feels that you have been exposed to carbon monoxide you will still receive any treatment or follow-up that is required.

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### **What other information will we need?**

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We will ask you for permission to consult your medical records (or other relevant medical records elsewhere) for some information relevant to your results. The information gathered will include your age, gender, ethnicity and if you have been diagnosed with dementia (we think there is a link between dementia and carbon monoxide exposure).

The qualified gas engineer that visits your home will complete a safety assessment form and return this information to the hospital so that we can understand the causes of carbon



monoxide exposure more clearly. If further work is required on any faulty appliance and your usual service provider is 'HomeServe', they will send us information from their engineer reporting form if you agree. This will give us additional information about carbon monoxide exposure.

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### **What are the benefits and risks of taking part in this study?**

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No health risks are anticipated. Although taking part in this study will not change your treatment, it is important to find out the extent of the problem of missed carbon monoxide exposure. If we find out that it is a significant problem, then an education system will be developed to teach doctors and nurses to test carbon monoxide levels in patients who suffer from these symptoms.

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### **What will happen to the results?**

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The results of this research are likely to be published in a medical journal and report, which will enable more people to benefit from the findings. All participants in the study will remain anonymous. If you would like to hear about the results, please let us know and we will write to you when they are available.

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### **Who is funding this study?**

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This study is being funded by the Gas Safety Trust. The Gas Safety Trust, established in 2005 as a registered charitable body, has become the UK's leading gas safety research charity. Their key objectives are further improving gas/fossil fuel safety for the public and industry throughout the UK and reducing the incidents of death and serious injury from carbon monoxide (CO) exposure. The Trust does this through the funding of research and data collection relating to carbon monoxide poisoning. More information on the Gas Safety Trust can be found on: [www.gassafetytrust.org](http://www.gassafetytrust.org), by email: [info@gassafetytrust.org](mailto:info@gassafetytrust.org) or by telephoning: +44 (0)20 7706 5111.

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### **What if there is a problem?**

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*Complaints:* if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then please speak with the researchers who will do their best to answer your questions or concerns. Alternatively you can contact the hospital's Patient Advice and Liaison Service (PALS) on 020 8725 2453, or on email: [pals@stgeorges.nhs.uk](mailto:pals@stgeorges.nhs.uk)

*Harm:* there is little risk of harm associated with taking part in this study as blood tests like we are proposing are often taken. Taking blood from you may cause temporary discomfort but is unlikely to cause any harm. In the event that something goes wrong and you are harmed because of this research and this is due to someone's negligence then you may



have grounds for legal action for compensation against the sponsor (St George's University Hospitals NHS Foundation Trust), but you may have to pay your legal costs. The normal NHS complaints mechanism will still be available to you:

<https://www.nhs.uk/nhsengland/complaints-and-feedback/pages/nhs-complaints.aspx>

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### **Will my taking part in the study be kept confidential?**

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If you agree to take part, your hospital doctor and GP will be informed of your participation in the study but otherwise your participation will be entirely confidential.

St George's University Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller. This means that we are responsible for looking after your information and using it properly

Only the relevant information mentioned above will be extracted from your records. These will be looked at by responsible individuals from the hospital, sponsor and/ or from regulatory authorities where it is relevant to your taking part in this research. Any information about you shared as part of this project will be anonymised with a code and will have personal details such as your name and address removed from it. The same will apply to the blood samples used in the laboratory studies. The information shared as part of this study will only be known by a unique research number, which will prevent external researchers from knowing your identity.

We are required to inform the National Gas Emergency Service if there is a risk of carbon monoxide leak within your home and information shared between the gas engineers and the referring hospital will be identifiable. Gas engineer forms that are returned to your referring hospital as part of the study will be destroyed once information is entered in to the study database. Any identifiable information will be kept within the local hospital. This hospital will keep identifiable information about you from this study for up to 10 years after the study has finished.

Research data is added to a secure, encrypted database which cannot identify you. As sponsor, St George's University Hospitals NHS Foundation Trust may keep this information collected for the purpose of this study up to 10 years after the study has finished. This is to ensure integrity of the results. All data will be stored in a secure manner.

Your rights to access, change or move your information are limited, as we need to manage the data in specific ways to ensure the research we conduct is reliable and accurate. If you withdraw your consent to participate in a research project, this will not mean we will have to remove all data as well. We will keep the information about you that we have already



obtained to ensure research integrity is maintained in the public's interest. To safeguard your rights, we will strive to use the minimum personally-identifiable information possible.

You can find out more about how we use your information

<https://www.stgeorges.nhs.uk/education-and-research/research/research-privacy-notice/>

For general information on how the NHS uses research data please visit

<https://www.hra.nhs.uk/information-about-patients/>

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### **Who has reviewed this study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect the interests of patients and participants. This study has been reviewed and given favourable opinion by London-Queen Square Research Ethics Committee (18/LO/1381).

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### **If I agree to being part of this study, what happens next?**

You will be given a copy of the information sheet and a signed consent form to keep.

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### **Further Information and contact details**

If you require any additional information or have any additional questions, further information can be found on our study website <https://www.stgeorges.nhs.uk/edco/>. Alternatively, please feel free to contact your doctor or the study lead.

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