PARTICIPANT INFORMATION LEAFLET

DOES HAVING REGULAR FOLLOW-UP AFTER SURGERY LEAD TO EARLY DETECTION OF THE CANCER RETURNING, RESULTING IN IMPROVED SURVIVAL AND BETTER QUALITY OF LIFE IN PATIENTS WHO HAVE HAD GULLET OR GASTRIC CANCER REMOVAL?

SARONG

SURVEILLANCE AFTER RESECTION OF OESOPHAGEAL AND GASTRIC CANCER (SARONG) STUDY

SUMMARY AT A GLANCE

WHY ARE WE DOING THE SARONG STUDY?

We want to find out if having more surveillance visits including extra clinic visits and regular scans will help us to detect any cancer returning at an earlier stage when it is more treatable and whether this leads to improved survival in patients who have been treated for gullet (oesophageal) or gastric (stomach) cancer.

WHO CAN TAKE PART?

Patients who have been treated with surgery for oesophageal and stomach cancer.

WHAT WILL HAPPEN IF I TAKE PART?

After you have had surgery for your cancer, we will check if you are eligible to join the study. If you consent to take part we will ask you to fill in some questionnaires. You will then be placed, by chance through a process called randomisation, into one of two groups as outlined below. Neither you nor your doctor can decide which group you get placed in to ensure that there is a fair and equal comparison between both groups. Patients in both groups will be asked to complete some further study questionnaires after 6, 12, 18, 24, 30 and 36 months.

Group 1
Clinical review will be performed at 6 and 12 months.
After 12 months you will be either discharged to primary care or clinically reviewed annually by the treating centre.

OR

Group 2
Clinical review including CT scans every 6 months for 3 years.
Endoscopy will be performed at 12 months post-randomisation.

HOW LONG IS THE SARONG STUDY?

You will take part in the study for **36 months in total**.

WHO IS FUNDING AND ORGANISING THE SARONG STUDY?

The SARONG Study is funded by the National Institute for Health and Care Research (NIHR) and is run by the University of Oxford.

We would like to invite you to take part in our study (called a clinical trial). Before you decide whether you would like to take part, it is important that you understand why the study is being done and what it would involve for you.

Please take time to read this information, and discuss it with others (e.g. GP, family members, charity, etc.) if you wish. If there is anything that is not clear, or if you would like more information, please ask your local study team at the hospital, or contact the SARONG study team directly. The contact information is at the end of this leaflet.

What is the purpose of the study?

We want to find out if having more follow-up visits including regular scans every 6-months over a period of 3 years and an endoscopy at 12 months, will help detect any return of cancer at an early stage when it is more likely to be treatable in people who had surgery for oesophageal or stomach cancer.

Why have I been invited to take part?

You have been invited to take part because you have recently had surgery for gullet (oesophageal) or gastric (stomach) cancer with or without chemo(radio)(immuno)therapy.

The SARONG study aims to recruit 952 people from NHS hospitals across the UK, aged 16 years and over who have received surgery for gullet (oesophageal) or gastric (stomach) cancer with or without chemo(radio)(immuno)therapy. If you have another cancer (other than oesophageal or stomach) and are undergoing treatment or surveillance you will not be eligible to take part.

Do I have to take part?

No, it is completely up to you. The study is voluntary and you are under no obligation to take part.

Deciding not to take part will not affect the treatment or care you receive. If you choose not to join the study, you will receive your NHS treatment in the usual way, as agreed by you and your treating team of healthcare professionals.
Should you decide to take part, you are still free to withdraw at any time and without giving a reason and withdrawal will not affect your clinical care.

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

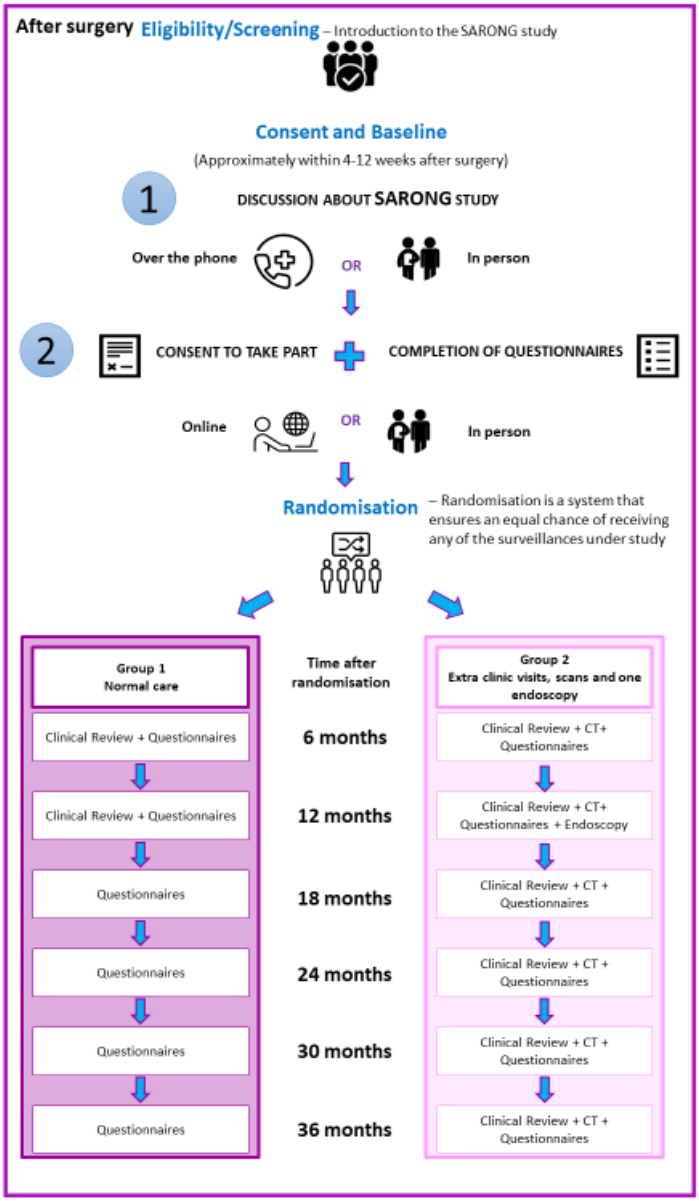
After surgery for oesophageal or stomach cancer, normally you would have a post-surgical clinic visit with your hospital around 4 to 12 weeks after your operation and then another follow-up at 6 months and 12 months after your operation. In the SARONG study, we want to see if it is beneficial to patients to have more frequent clinic visits and scans after this type of cancer surgery.

If you agree to join the SARONG study, you will be asked to sign the SARONG study consent form. A member of the study team will then ask you about your medical history and medications, and collect some information from your medical records about your diagnosis and surgery and ongoing treatment. You will be asked to fill in some questionnaires about your health-related quality of life. You can decide if you would like to fill in the questionnaires on paper or online via a secure study website.

You will then be randomised (allocated by a computer) into either group 1 (standard of care: normal clinical visit schedule) or group 2 (intervention: extra clinical visits with scans and an endoscopy).

- If you are in **group 1**, you will receive standard of care which includes a clinical review at 6 and 12 months, and after 12 months you will be either discharged to primary care or clinically reviewed annually by your treating centre.
- If you are in **group 2**, you will have a clinical review with a chest/abdomen/pelvis CT scan every 6 months for up to 36 months (3 years). An endoscopy will also be performed 12 months. You will be informed of any findings from your additional scans by your clinical care team in the normal way, and any further treatment given as per standard of care pathways.
- If you have a CT scan and it shows that your cancer has returned, this result will be discussed with you by your local treating team, and further treatment will be arranged in accordance with local practice.
- You will also be asked to complete questionnaires at 6, 12, 18, 24, 30 and 36 months. These should take 30 minutes to complete each time but slightly longer at the first and last timepoints as we will ask a few more questions about your overall health. They are really important for our study.

Study flow chart



Randomisation

What is Randomisation?

SARONG is a randomised study. In this type of study, there is a direct comparison between participants who have extra clinic visits and scans or participants who have the standard number of clinical visits and scans. The only way we can compare these is by dividing participants into two groups that are as similar as possible by a process called randomisation. Randomisation means that patients who agree to participate in the study are randomly allocated to one of the surveillance groups. It is important that you only agree to take part if you are prepared to accept either extra clinic visits and scans or the standard NHS care visits.

GROUP 2

Clinical Review

During the clinic visit, the study team will check your current medications and ask if there have been any changes in your health since your last visit.

CT-scan

"CT-scan" stands for computerised tomography (CT) scan and the equipment uses X-rays and a computer to produce images of the inside of the body. For this study, CT scans of the chest, the abdomen and pelvis will be performed. These are routine scans performed in the NHS and you may have had one before.

Preparing for a CT scan: Avoid eating anything for several hours before your appointment.

Before having a CT scan: In order to obtain a good quality of the images, you are given a contrast agent (special dye) in the form of a drink or injected into a blood vessel. The contrast injection contains iodine, which can cause an allergic reaction in a few people. You should tell the Radiographers who are carrying out the scan if you have had an allergic reaction to iodine or contract dye in the past, or if you have any other allergies. Very rarely the dye may cause some kidney damage in people who already have kidney problems. There is a small chance that the contrast injection can leak outside the vein and cause temporary swelling and discomfort in the arm; this does not happen very often. In the unlikely event of this happening, the study team will provide you with further instruction and advice.

During a CT scan: You will lie on a bed in a well-lit, spacious room. The bed will pass into a wide 'doughnut' shaped part of the scanner. You simply lie still and take a deep breath while images are taken. This should take about 10 minutes in total.

After a CT scan: You should not experience any after-effects.

Please also refer to your local hospital information leaflet concerning CT scans for further information.

Endoscopy

Endoscopy is a test using a camera to look inside your body. For this study, if you are in the group that has extra clinic visits, an endoscopy will also be performed, a long thin tube with a small camera will be passed down your throat to check your oesophagus and stomach.

Preparing for an endoscopy: On the day of the endoscopy, you'll need to stop eating at least 6 hours before the test.

During an endoscopy: The thin tube with the camera goes into your mouth and down to your stomach, you may feel a bit discomfort, this will stop once the tube reaches your stomach.

After an endoscopy: You may have some stomach and throat soreness after an endoscopy. This is normal and should pass in a few hours.

Please also refer to your local hospital information leaflet concerning upper gastrointestinal endoscopy for further information.

Participant questionnaires

SARONG is looking at the quality of life of patients affected by oesophageal or gastric cancer. The study questionnaires will ask you about your general health and wellbeing, and your use of health care services.

The information you give is really important as it helps us to understand your quality of life over the course of the study. They are electronic questionnaires, but you may be given a paper version if you prefer. The questionnaires will take about 30 minutes to complete, with the first and last questionnaires being slightly longer.

If you take part in this study, it may be useful to make a note of your medical appointments related to your cancer and your surgery (i.e. GP/Nurse visits, pharmacy appointments) as we will ask you about this information in the follow up questionnaires.

Are there any possible disadvantages or risks from taking part?

If you are allocated to the group 2 you will have additional CT scans of your chest, abdomen and pelvis, and clinical visits, which will involve additional time in the hospital as an outpatient. You will also have an upper gastrointestinal endoscopy at 12 months; this procedure does carry potential risk of injury to the oesophagus or stomach (less than 5 in 100). CT scans use ionising radiation to form images of your body and/or provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous.
The chances of this happening to you as a consequence of taking part in this study are 0.5%.

What are the possible benefits of taking part?

There may be no direct benefit to you as a result of taking part in this study, however if you are allocated to group 2 and have more regular visits including scans and an endoscopy this may result in us being able to detect any cancer returning sooner. In addition, it is hoped that the information gained from doing this study will help us understand how to better follow-up people treated for oesophageal and stomach cancer in the future.

Will my General Practitioner/family doctor (GP) be informed of my participation?

Yes, with your permission, we will inform your GP about your participation in the study.

Will my taking part in the study be kept confidential?

Your local study team will use your name, date of birth, NHS number (or Community Health Index number in Scotland) and contact details to keep you informed about the study and to enable follow up. If you decide to receive the questionnaires by post, the central study team will have access to your identifiable information in order to send you the questionnaires. Your identifiable information will be kept confidential by the local and central study team and store for up to 12 months after the study has finished.

If you take part of the study, you will be given a unique participant identification (ID) number and all data and results will be stored using this, instead of your name or any other identifiable personal information. All the information through medical notes and questionnaires that is collected about you during the course of the study will be kept strictly confidential and it will not be possible for anyone else to identify the results as yours, or to identify who you are from your data. Your CT scans will be shared with the study team at the University of Oxford for quality assurance purposes. Scans will be transferred and kept securely and will

be labelled with your study ID only. These CT scan images and other data, once anonymised, may be used in other studies.

Your personal identifiable information will be stored at the University of Oxford in a secure password-protected database, accessible only to the study team. Responsible members of the University of Oxford and relevant NHS Trusts may be given access to data for monitoring and/or audit of the study to ensure that our research is complying with applicable regulations.

Will I be reimbursed for taking part?

No, you will not be reimbursed for taking part in the study.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford, based in the United Kingdom, is the data controller and is responsible for looking after your information and using it properly.

All data will be stored and used in compliance with the relevant, current data protection laws (Data Protection Act 2018; UK General Data Protection Regulation (UK GDPR 2018). Further information is provided below, and you will need to indicate on the consent forms that you understand this.

We will be using information from you and your medical records NHS England and other central NHS registries in order to undertake this study and will use the minimum personally-identifiable information possible.
We will use the minimum possible personally identifiable information, and this will be kept for 12 months after the study has finished. Non-identifiable research data and any research documents with personal information, such as consent form, will be stored securely at the University of Oxford for a maximum of 3 years after the end of the study, as part of the research record.

The local study team will use your name, NHS/CHI number and contact details, to contact you about the study, and to look at your relevant medical history. They will keep study documents with personal information, such as consent forms, for a maximum of three years after the study has finished or as per local Trust policy for medical notes retention. All other identifiable data will be destroyed 12 months after the end of the study unless you agree to us retaining these for future contact.

We would like to be able to contact you in the future about ethically approved research studies, we will ask for your consent to do this. If you agree to your details being held to be contacted regarding future research, we will keep the consent form and your contact details separate. All contact regarding future research will come from the research team at the University of Oxford in the first instance. Agreeing to be contacted does not oblige you to take part in future research, and you can be removed from this register at any time you wish. If you agree to your details being held to be contacted regarding future research, the University of Oxford will hold your consent form and your contact details indefinitely or until you withdraw from future contact.

We may disclose your personal data to our third-party service providers to carry out activities specifically for the purpose of this research and as explained in this information sheet. Any third-party service providers are required to take appropriate security measures to protect your personal data in line with University of Oxford policies. We do not allow our third-party service providers to use your personal data for their own purposes, but rather to only process your personal data for specified purposes and in accordance with our instructions.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your persona data is available at https://compliance.web.ox.ac.uk/individual-rights.

You can find out more about how we use your information by contacting sarong@nds.ox.ac.uk.

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

If you decide to take part in the study, you are free to withdraw at any time and without giving a reason. Withdrawal from the study will not affect the standard of care you receive.

If you would like to withdraw, please inform a member of the SARONG team at your hospital and they will discuss your withdrawal options with you – you will need to have your study ID (this can be found at the top of the consent form that you signed).

Your data are valuable to our research, and we would like to use the data already collected up until the time you withdraw, as well as continuing to collect data on any future hospital admissions and outcome.

What will happen to the results of this study?

We intend to publish the results of the SARONG study in medical journals, and to present the results at conferences and updates of study news will be made available on the website (sarong.octru.ox.ac.uk) and via social media. Please note that it will never be possible to identify you from any report or publication placed in the public domain.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study. 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, or how your information is handled during the course of this study, you should contact the Chief Investigator, Prof Sheraz Markar at sarong@nds.ox.ac.uk, or you may contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) office on 01865 616480, or the head of RGEA, email RGEA.complaints@admin.ox.ac.uk.

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. If you would prefer to speak with someone who is not involved in the study, please contact your local PALS.
In Scotland you can contact The Patient Advice and Support Service (PASS) by visiting the PASS website at www.patientadvicescotland.org.uk and use webchat or by calling the PASS national helpline on 0800 917 2127.

How have patients and the public been involved in this study?

Patients and the public have been actively involved in the ideas design, and development of this trial. One patient supporter has been involved from the outset and has reviewed, commented on and helped improve all the trial documentation. Patients helped develop the research topic and what research questions should be asked through our patient advocate. In designing this study, we also considered patient opinions on the frequency of participant visits and the tests that we should carry out.

Who is organising and funding the study?

SARONG has been funded by the NIHR Health Technology Assessment Programme (part of the Department of Health & Social Care) and is led by the University of Oxford.

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 participants' interests. This study has been reviewed and given favourable opinion by North West - Haydock Research Ethics Committee.

Further information and contact details

If you would like to speak to someone about the SARONG study please contact your hospital team or contact the SARONG study team at the University of Oxford by e-mail sarong@nds.ox.ac.uk or telephone + 44 (0) 7407 894087.

Thank you for reading this leaflet and considering taking part.

SARONG