<<insert trust logo here>>

Place local research team details sticker here	Place local PALS details sticker here

IRAS Number: 242342

The Sunflower Study

Participant Information Leaflet

Testing for bile duct stones before gallbladder surgery

You have been sent this information because you have either been referred to hospital as you are experiencing problems with your gallbladder or because you are expecting treatment for your gallstones. One of the possible treatments for patients with gallbladder problems is surgery. At the hospital we are taking part in a study into whether testing for bile duct stones before gallbladder surgery is necessary or not. We realise that your treatment may not yet have been decided, but if you are referred for gallbladder surgery you may be invited to take part in this study. We are therefore sending you this information to help you consider whether you'd like to take part in our research study should you have gallbladder surgery. We have also developed a short video about the study, which you can view online at <insert URL>. If you are referred for surgery, a member of our team will talk to you about this study once you have spoken to the surgeon. They will go through this leaflet with you, explain the study in more detail and answer any questions you have. **A diagram summarising what will happen if you take part can be found on page 3.**

Taking part in research is voluntary. You do not have to take part. If you choose to take part, you are free to withdraw at any time. You do not have to give any reason for your decision. The standard of care you receive will not be affected.

Before you decide whether you would like to take part or not, we would like you to understand why the study is being done and what it would involve. Please read the following information carefully. Talk to others, such as friends or relatives, if you wish and take time to decide. If anything is not clear or you would

like more information, please contact us using the contact details on the back of this leaflet.

What is the purpose of the study?

Some patients who are waiting for gallbladder surgery may also have gallstones that have moved into the bile duct. Currently, it is uncertain whether testing for bile duct stones in these patients is necessary; some doctors test for bile duct stones and others do not. Both options are considered standard routine care. This study will find out whether it is necessary to test for bile duct stones in patients waiting for gallbladder surgery. We will compare what happens to patients who are tested for bile duct stones with patients who are not. We will also investigate whether testing for bile duct stones provides value for money for the NHS. We hope to enrol approximately 13,700 patients into the study.

Bile duct stones

A small number of patients (approximately 2-5 patients in every hundred or 2-5%) who are waiting for gallbladder surgery will experience problems with bile duct stones. These problems include pain, jaundice (yellowing of the skin) and inflammation of the pancreas (pancreatitis). If this happens, it may be necessary to remove the bile duct stones before the gallbladder operation. It is not possible to know at the moment whether you have bile duct stones.

Testing for bile duct stones

To test for bile duct stones, a special scan called a magnetic resonance cholangio-pancreatogram (MRCP) may be undertaken before gallbladder surgery. The scan involves a magnetic resonance imaging (MRI) scanner, which is a type of imaging system that uses magnetic fields and radio waves to build up a detailed image of your bile duct and surrounding organs. It is a large tube that contains powerful magnets. You lie inside the tube during the scan. The scan does not involve injections and is usually very safe, with no exposure to radiation, and the risk of serious complications is very low. The scan usually takes approximately 15-20 minutes. If the scan shows bile duct stones, it is usual for them to be removed before gallbladder surgery.

Removing bile duct stones

Stones are usually removed via an endoscope procedure that takes place in hospital. Before the procedure, you may be offered a sedative to help you relax. The endoscope is a narrow flexible tube with a camera on it. It is passed through your mouth, down your throat and gullet (oesophagus), into your stomach and into the small intestine (duodenum) to look at your bile duct. If bile duct stones are still present (and have not spontaneously passed into the bowel since having the scan), they will be removed. The procedure is called an endoscopic retrograde cholangio-pancreatography (ERCP) and involves a day in hospital and often a stay overnight.

What will I have to do if I take part?

Consent

You will need to take the time to read this leaflet and understand what the study would involve. You can speak to the research team who will answer any questions you may have. If you decide to take part, you will be asked to sign a consent form. The study team may ask if you wish to complete a consent form in person, or on a form posted to you, depending on how they are contacting you. They may also offer to take your consent online.

If you choose to consent via post or online you will have a chance to speak to a member of the team about the study on the telephone. For online consent you will need to share your email address with the local research team and they will remain on the call while you complete an online form on a secure database. Your email address will be stored on a University of Bristol server if you decide to take part, but your participation will be kept confidential.

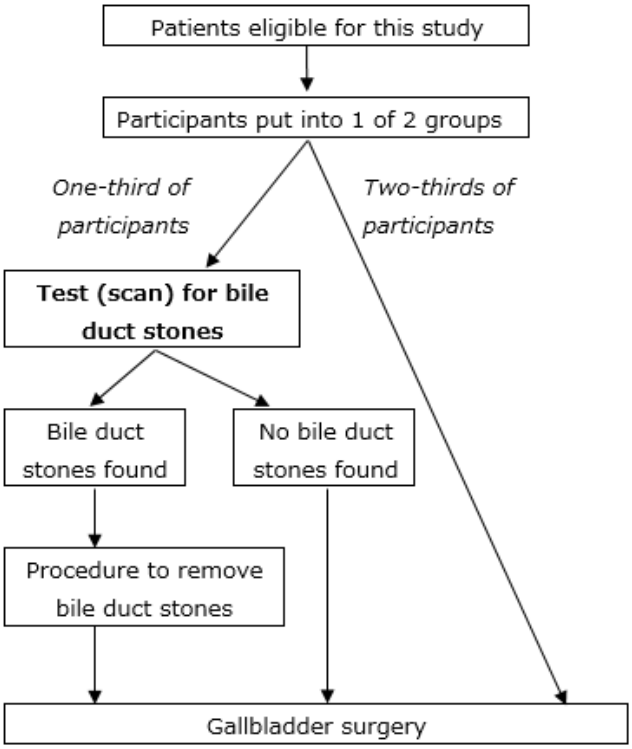
However you choose to consent to the study, you will be given a copy of your consent form to keep for your records.

So that we can evaluate the information we give to participants about the study, we may ask your permission to audio-record these consultations. If so, you will be given a separate information sheet that describes this in more detail. If you agree to your consultation being audio-recorded, we will ask you to sign a separate consent form.

Randomisation

We will put everyone who takes part in the study into one of two groups. To try to make sure the groups are the same to start with, people will be put into a group randomly so that neither you or the study team will select which group you will be in. One group will have the scan to test for bile duct stones before their gallbladder surgery and the other group will not. The group that have the scan will be half the size of the group who do not to limit the number of scans performed in the study. Whichever group you are put into, the care you will receive is considered part of standard routine care that takes place all over the NHS, and every other aspect of your care will be the same.

Diagram summarising what will happen if you take part in the Sunflower Study



Treatment

If you are in the group of people having a scan to test for bile duct stones, you will be given an appointment at your hospital to have the scan before your gallbladder surgery either as an outpatient or an inpatient depending on whether you are already staying in hospital.

Progress review

We will collect information about your medical history before your gallbladder surgery and will review your progress until you are discharged home. We will also collect information about any hospital admissions you make for between 1-4 years after your operation, depending on when you joined the study.

Questionnaires

So that we can record how you are feeling before and after your operation, you may be asked to complete questionnaires. Not all participants will be asked to do this, and it will be decided at random. This is because we do not need all participants to fill in questionnaires to have enough information to answer this part of the research question. If you are selected, we will ask you to complete the questionnaires at the time you start the study, at the time of your gallbladder surgery, and approximately 3, 6 and 12 months after joining the study. Some participants will also complete questionnaires 18 months after joining the study. You can choose to do them by post or electronically (online). The questionnaires give us information about your health; for example, how you are feeling, what activities you can perform and how much pain you are feeling. They shouldn't take more than approximately 10 minutes to complete.

What alternatives are there to taking part?

If you decide not to take part in the study, you will receive the usual care provided in your hospital, which may or may not include having a scan.

What are the possible benefits of taking part?

We cannot promise that the study will help you, but we hope that the results from this study may help benefit the NHS and improve the management of future patients. Possible advantages of taking part are listed on the next page.

What are the possible disadvantages and risks of taking part?

A summary of the advantages and disadvantages of testing versus not testing for bile duct stones is provided on the next page.

If you take part in this study, you may have to undergo an endoscopic procedure (ERCP) or imaging of your bile duct (intraoperative cholangiogram). Some of these will be extra to those that you would have if you did not take part. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. We are all at risk of developing cancer during our lifetime. The normal risk is that this will happen to about 50% of people at some point in their life. Taking part in this study will add only a very small chance of this happening to you.

Table summarising possible advantages and disadvantages of testing and not testing for bile duct stones

Testing for bile duct stones	**Not testing for bile duct stones**
Possible advantages • May detect and, if needed, treat bile duct stones that may become a problem. **Possible disadvantages** • For approximately 5-10 in every hundred patients (5-10%), the scan may not detect bile duct stones even though they are there because they are too small to be seen. This means that some patients may have bile duct stones left behind after their gallbladder surgery, which could cause problems (e.g. jaundice, infection or pancreatitis) that require further treatment or readmission to hospital. • Bile duct stones often pass safely and spontaneously into the bowel meaning the scan and procedure to remove them will have been unnecessary. • Some patients may experience claustrophobia (fear of enclosed spaces) during the scan. • For some patients, the scan and the endoscope procedure (if required) may mean waiting longer for your gallbladder surgery, which may lead to problems with gallstones while waiting. The surgery will not always be delayed.	**Possible advantages** • Allows gallbladder surgery to go ahead without the possible disadvantages of testing for bile duct stones. **Possible disadvantages** • Any bile duct stones that are present are not detected. • Undetected bile duct stones may cause problems after your gallbladder surgery (e.g. jaundice, infection, pancreatitis) and require further treatment or readmission to hospital. We estimate this to happen to approximately 2-5 patients in every hundred (2-5%). • If bile duct stones are suspected later, a scan and, if required, an endoscope procedure will likely be needed to remove them.
Risks of the endoscope procedure to remove bile duct stones	
The following can occur: pancreatitis (approximately 3-4 patients in every hundred or 3-4%), bleeding (approximately 1 patient in every hundred or 1%), bowel perforation (a small hole in the bowel) (approximately 1 patient in every hundred or 1%) or infection. Occasionally, the endoscope procedure may show a bile duct that is clear of stones, suggesting the stones have spontaneously passed into the bowel since having the scan and meaning the procedure to remove them was unnecessary. Some patients may not have an endoscope procedure but will have a slightly different procedure or small operation instead. If this is the case for you, this will be explained.	

What if there is a problem?

If you have any concerns or questions about this study, please contact the research team listed on the back of this leaflet.

If you have concerns about the way you have been treated during the study or wish to make a formal complaint, you may wish to contact the Patient Advice and Liaison Service (PALS). Please see their details on Page 1 of this information leaflet.

We have no reason to believe that you will be placed at any greater risk to your health by taking part in this study. However, if something goes wrong and you are harmed during the study there are no special compensation arrangements. If anything goes wrong because of taking part in the study due to negligence, the NHS trust responsible will compensate you. Negligence includes, for example, if injury was caused by a deviation from the study protocol by a researcher. The normal NHS complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

Leeds Teaching Hospitals NHS Trust is the Sponsor for this study and the University of Bristol is the substantive employer of the study coordination team who are based at the Bristol Trials Centre (BTC). Both organisations will use information from you and your medical records in order to undertake this study and will act as the joint data controllers for this study. This means that they are responsible for looking after your information and using it properly. The University of Bristol and University Hospitals Bristol and Weston NHS Foundation Trust will process your personal data on behalf of the data controllers, in their role as data processors. Your local hospital site and the central coordinating team in Bristol will keep identifiable information about you for 5 years after the study has finished.

Your local recruiting hospital will collect information from you and your medical records for this research study and will transfer it securely to the coordination team at BTC in accordance with our instructions. All your data will be stored securely on an NHS server.

Your local recruiting hospital and BTC will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. They may also check your address against NHS records to ensure that the details they have for you are up to date. Occasionally, other members of NHS staff or research staff at your local recruiting hospital may need to check your medical records but this will only be done by researchers bound by the same rules of confidentiality as all NHS staff. The confidentiality of your medical records will be respected at all times. All the information collected will be stored in a purpose built and secure database. Individuals from the Sponsor and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your local recruiting hospital and BTC will keep your name and contact details confidential. The only people in the coordinating centre who will have access to information that identifies you will be people who need to contact you as part of the Sunflower Study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details.

If you agree to take part in the Sunflower Study, we will also collect some data about you from the NHS Wales Informatics Service. This database contains all inpatient and day case activity undertaken in NHS Wales plus data on Welsh residents treated in English Trusts. All this information is routinely collected by the NHS whenever you have hospital treatment. We will use some data which includes information about any stay in hospital you may have. This will allow us to see if you have required any hospital care since you entered the study. We will also obtain mortality data. The NHS Wales Informatics Service will link your NHS number to mortality data which will provide information about any deaths of participants that occur during this research. To obtain information from the NHS Wales Informatics Service and mortality data, we need your permission to share your full name, gender, NHS number, postcode and date of birth with them and they will send the information back to the University Hospitals Bristol NHS Foundation Trust.

Any information about you will only be used for the purposes of this research unless you give permission for it to be used in future ethically approved studies. You can still take part in the Sunflower Study if you do not want your data to be used for other studies. If you do consent to your data being stored for use in future studies, any identifiable information will be stored on secure NHS servers. Stored identifiable information will not be passed on to any third party. Information collected about you without any identifiers will only be shared with researchers who have ethical approval for their research.
We may also need to contact your GP to obtain information relevant to our research. To enable us to do this, we will ask for your consent for your GP to be informed that you are participating in this study.

What if new information becomes available?

If we get new information about the management of bile duct stones, your doctor will let you know and discuss whether you want to continue in the study.

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

You are free to withdraw from the study at any time without giving a reason and this decision will not affect your rights. You may be happy to continue with the questionnaires (if applicable), or you may want to withdraw from the study completely. This will be discussed with you at the time of withdrawal.

You can withdraw in writing, by telephone, or in person by contacting your local research team (details on Page 1) or the study coordinating centre (details on Page 8).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. This means that we won't be able to let you see or change the data we hold about you. If you withdraw from the study, we will keep and use the information about you that we have already obtained.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital and the NHS Wales Informatics Service, without contacting you. If you do not want this to happen, tell us and we will stop. To safeguard

your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at https://sunflowerstudy.blogs.bristol.ac.uk/privacy-notice/ or by contacting the SUNFLOWER team.

Who is organising and reviewing the study?

This study has been reviewed by an independent Research Ethics Committee, who protect your safety, rights, wellbeing and dignity. Leeds Teaching Hospitals NHS Trust has overall responsibility for the study. The study is managed by BTC. This study is funded by the National Institute for Health Research - Health Technology Assessment Programme (16/142/04).

Further information

It is unlikely that any insurance would be affected by taking part in this study, but you should consider this before consenting and seek advice if necessary.

You can obtain general advice on surgery from: http://www.nhs.uk/conditions/surgery/Pages/Introduction.aspx

You can obtain general information on clinical research from the UK Clinical Research Collaboration who produce a booklet called 'Understanding Clinical Trials' which can be requested by email: crncc.info@nihr.ac.uk or online: http://www.ukcrc.org/public-awareness-of-clinical-research/information-resources-on-clinical-research/

Contact details

Coordinating centre

SUNFLOWER Study

Bristol Trials Centre

1-5 Whiteladies Road

Bristol

BS8 1NU

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Thank you for reading this leaflet and considering taking part in our study

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