C-GALL

PATIENT INFORMATION LEAFLET

The purpose of this study is to compare keyhole gall bladder surgery (laparoscopic cholecystectomy) with medical management in people who suffer from pain due to gallstones but do not have other complications.

INVITATION TO TAKE PART

We would like to invite you to take part in a research study related to gallstones.

Before you decide if you would like 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, discuss it with your family, friends, or G.P. if you wish. Please do not hesitate to contact us if there is anything that is not clear or if you would like more information. Contact details are on the back of this leaflet.

BACKGROUND

Gallstones are very common, with about 10-15% of UK adults suffering from gallstones. However, only 1 in 5 people with gallstones develop symptoms and require medical treatment. The most reported symptom is pain (known as 'biliary colic') in the upper right-hand side of the abdomen. Some people may also suffer from inflammation of the gallbladder (cholecystitis). Painkillers and occasionally antibiotics are prescribed to control gallstone symptoms and surgery is often advised for medically fit patients.

Surgery to remove the gallbladder, known as cholecystectomy, remains the most common treatment. Approximately 70,000 surgical operations for the treatment of gallstones are performed every year in the UK, with significant costs for the NHS.

In the UK, surgery is commonly offered to medically fit people who present at hospital with symptoms or complications due to gallstones. However, up to half of people may not have further symptoms after their initial episode of pain and so surgery may not be necessary. A policy of 'medical management' (painkillers/antibiotics and lifestyle advice) could, therefore, be all that is needed for some people, as they may not experience further episodes of pain.

WHAT IS THE PURPOSE OF THE STUDY?

Most of the current research on gallstones focuses on the surgical management of the disease, less research has been done on 'medical management'. Doctors and surgeons agree that for people who do not have complications there is now a need for a clinical study, which compares surgical management with medical management. This clinical study will help surgeons, patients and health services decision makers understand which is the most effective treatment for people who suffer from pain due to gallstones, but do not have other complications.

This UK-wide study will collect data from 430 patients over 18 months following either surgical management or medical management, to see if these two procedures get similar results.

DO I HAVE TO TAKE PART?

No. It is entirely up to you whether or not you take part.

Please take as much time you need to make this decision.

You can read this information leaflet as many times as you wish and ask your doctor (GP or hospital doctor) and/or research nurse as many questions as you like.

If you do decide to take part you will be asked to sign a form giving your consent to be included in the study. You are free to withdraw from the study at any time without giving a reason. Your decision will not affect the standard of care you receive now or in the future.

WHAT WOULD TAKING PART INVOLVE?

The clinical team (doctor, surgeon, research nurse) in charge of your treatment will give you full information about the study either by discussing it with you in person or by sending you this detailed information booklet by post. If appropriate, a member of the local research team will discuss the study with you at the clinic or contact you by telephone to give you more information and answer any queries you may have.

After taking your time to consider the study and if you agree to take part you will be asked to sign a consent form. You may be asked if your consultation with your consultant can be audio recorded.

Randomisation:

The particular treatment given to each person in the study will be decided by a computer allocation. If you decide to take part in this study, this will mean that neither you nor your doctors can decide which treatment you will receive. There is an equal chance you will be placed into either treatment group.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

You will receive the same health care from your doctors whether or not you choose to participate in the study. By taking part, you will be directly helping us to inform the future treatment of people with uncomplicated gallstones. The results of this study will help plan effective services offered by the NHS in the future.

WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Risks and complications are possible from both surgical treatment and medical management and participation in this study should not increase those risks.

If you are allocated to the surgical option, a competent and trained surgeon will perform your operation. There are risks associated with surgical procedures and anaesthetics. The team responsible for your care will explain these to you. If you are randomised to the medical management option, then your GP will keep an eye on your symptoms and will keep the surgical team informed if there is any change.

WHAT ARE THE SIDE EFFECTS OF ANY TREATMENT RECEIVED WHEN TAKING PART?

In the UK, surgery is commonly offered to medically fit people presenting with symptoms or complications due to gallstones. However up to half of people with uncomplicated gallstone disease, may not have further symptoms after the initial episode of pain for up to 10 years, and surgery may not be necessary. It is well known that surgical option carries a 10% risk of major and minor complications. Moreover, up to 20% of people who have surgery still experience pain and require on-going pain management. A policy of medical management (painkillers/antibiotics and lifestyle advice) is suggested in this group of people.

In describing the size of a risk, some patients have found the table below a useful way to interpret the numbers.

Term	Equivalent numerical ratio	Equivalent environment
Very common	1/1 to 1/10	One person in a **family**
Common	1/10 to 1/100	One person in a **street**
Uncommon	1/100 to 1/1000	One person in a **village**
Rare	1/1000 to 1/10,000	One person in a **small town**
Very rare	Less than 1/10,000	One person in a **large town**

GENERAL RISKS OF SURGERY

Any surgical procedure has its risks and potential problems. The following are possible problems that you may experience:

- **Anaesthetic risks:** This is rare unless you have specific medical problems. Death is very rare. Your anaesthetist will discuss with you in detail.
- **Bleeding:** The risk of major bleeding, which is severe enough to need a blood transfusion, is uncommon but it can happen with any operation.
- **Infection:** The risk of infection at any of the wound sites is common, and you might receive antibiotics in theatre to reduce such risk. Serious hospital-acquired infections (e.g. MRSA and Clostridium Difficile) are rare.

- **Deep Vein Thrombosis (DVT):** A clot in the deep veins of the leg. While the overall risk is common (4-5%), the majority pass unnoticed and resolve spontaneously. It is rare for a clot to migrate to the lungs and cause serious problem following day-surgery (affecting less than 1% of those who get a clot). However, there have been deaths following such clots and, therefore, special stockings and/or injection to thin the blood are provided to all patients.

SPECIFIC COMPLICATIONS OF A CHOLECYSTECTOMY

Complication	Risk
Injury to the bowel	0.1% (uncommon)
Bile leak (requiring further surgery, endoscopy)	1-3% (common)
Injury to the bile duct	0.2% (rare)
Major bleeding (>500 ml)	1-2% (common)
Post-operative collections requiring antibiotics or drainage	1-3% (common)
Re admission to the hospital	5% (common)
Hernia at the site of port insertion	1% (common)
Severe biliary type pain persisting after surgery	4-9% (common)
Post cholecystectomy diarrhoea	10-15% (common)
Post cholecystectomy syndrome. (Persistent pain requiring further investigations to look for other causes)	13-37% (common)

POSSIBLE COMPLICATIONS FOR PEOPLE ON MEDICAL MANAGEMENT

There is a 0.7% per year risk (uncommon) of developing any of these complications for people on medical management*. (Life time risks are mentioned in the table below.)

Complication	Lifetime risk
Acute inflammation of gallbladder (acute cholecystitis)	10-20% (common)
Infection/pus in gallbladder (empyema)	5-10% (common)
Inflammation of pancreas (acute pancreatitis)	2-5% (common)
Stones in bile duct with or without jaundice	15% (common)
Perforation of the gallbladder	1-2% (common)

*People with gallstones and without symptoms (asymptomatic gallstones) who are NOT offered surgery are also susceptible to 0.3% per year risk (uncommon) of developing similar complications.

If any of these symptoms occur urgent medical attention is required.

It is well known that gallstones, irrespective of symptoms, can cause complications (e.g. pancreatitis/jaundice etc.) and in a minority of people (0.7% risk per year), an emergency hospital admission and further surgical treatment or specific medical procedures may be needed (endoscopy).

WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

If the study is stopped earlier than expected for any reason, you and your doctor will be informed and your continuing care will be arranged.

WHAT IF THERE IS A PROBLEM?

We do not expect any harm to come to you by taking part in this study. All procedures and techniques are already being used in the NHS to treat patients with uncomplicated gallstone disease. Your participation is only to help us evaluate these procedures and should not involve any **additional** risk to you.

If you have a concern about any aspect of the study, you can ask to speak with the research team who will do their best to answer your questions (contact details of your local study nurse and the Study Office can be found at the end of this information sheet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from your hospital.

If you believe that you are harmed by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of this study, the University of Aberdeen and NHS Grampian.

As a patient of the NHS, if you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for your legal costs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal NHS complaints mechanisms would be available to you.

If you become unable or unwilling to continue in the C-Gall study we would withdraw you from the study. If this happens we will keep the relevant information already collected about you for the study results. This information will remain confidential and will not be used for any other purpose.

WHO WILL KNOW I AM TAKING PART IN THE STUDY?

Only certain members of the research team will have access to your information in order, for example, to send you the questionnaires.

We will tell your GP you are taking part, with your permission.

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsor(s), the NHS Research & Development Department of your local hospital, and the Regulatory Authorities whose roles it is to check this research is properly conducted and the interests of those taking part in this study are protected.

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential, and will be held securely in accordance with the Data Protection Legislation. Your information will be stored using a unique study number for confidentiality and will be kept secure using passwords.

IF YOU AGREE TO TAKE PART:

The University of Aberdeen and NHS Grampian are the co-sponsors 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 for this study. This means that we are responsible for looking after your information and using it properly. The University of Aberdeen and NHS Grampian will keep identifiable information about you for 10 years after the study has finished.

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. If you withdraw from the study, we will keep the information about you that we have already

obtained. 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://www.abdn.ac.uk/about/privacy or by contacting the Data Protection Officer at the University of Aberdeen (dpo@abdn.ac.uk).

Staff at the hospital who have sent this information leaflet 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. Individuals from the University of Aberdeen and NHS Grampian and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Staff at the hospital who have sent this information will pass these details to the University of Aberdeen and NHS Grampian along with the information collected from you and your medical records. The only people in the University of Aberdeen and NHS Grampian who will have access to information that identifies you will be people who need to contact you to about study questionnaires 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.

Staff at the hospital who have sent this information will keep identifiable information about you from this study for 10 years after the study has finished.

In this study, we aim to collect relevant readmission hospital data from the NHS central registers: in England this is the Health and Social Care Information Centre [HSCIC], in Scotland this is the Information Services Division [ISD], and in Wales this is the NHS Wales Informatics Service [NWIS]. The reason for this is to make sure that we have the correct information about all the participants taking part in this study and ensure that the results are as accurate as possible. In order to do this, we would need to securely send the NHS central registers some information about you (e.g. date of

birth, name, and address). They will then match this information to their records and using your study number securely send any hospital readmission data back to the Study Office.

Other researchers may wish to access data from this study in the future, including from outside the UK. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth. The consultant leading the study will ensure that the other researchers comply with legal, data protection and ethical guidelines.

WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, the C-Gall Study Office staff will contact you to let you know about the choices available to you. However, we are not aware that any new, relevant information is likely to become available before the end of this study.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can decide at any time not to carry on with this study, but you should continue attending appointments with your consultant and/or GP as part of your standard care.

If you do withdraw from the study, all information collected up to the point of withdrawal will be kept and used in the analysis. We may also contact you again with a further invitation to take part in other relevant research.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of the study will be used to make recommendations on treatments for patients with uncomplicated gallstone disease. We shall publish the results of this study in scientific journals and present the information at appropriate meetings. You will not be

identified in any publication of results of the study. We will let you know the results of the study when it is finished unless you tell us that you do not wish to know.

WHO IS ORGANISING AND FUNDING THE STUDY?

The University of Aberdeen and NHS Grampian are the study sponsors and have overall responsibility for the management of the study. The UK government supported National Institute of Health Research (NIHR) Health Technology Assessment (HTA) programme funds the study. The research is being carried out by a group of experienced doctors and researchers and is managed from the Centre for Healthcare Randomised Trials (CHaRT), a UKCRC registered Clinical Trials Unit at the University of Aberdeen.

WHO HAS REVIEWED AND APPROVED THE STUDY?

This study has been approved by the North of Scotland Research Ethics Committee (2).

It is a requirement that your records in this study, together with any relevant medical records, are made available if requested by monitors from the Sponsors and the Research & Development Department of your local hospital, whose roles are to check this research is properly conducted and the interests of those taking part in this study are protected.

Other researchers may wish to access data from this study in the future. However, it will not be possible to identify participants from this data because it will not include names, addresses or dates of birth.

Thank you for reading this

Thank you for taking the time to read this information leaflet. We hope that it has been helpful in enabling you to decide if you would like to participate in the C-GALL study. Please ask us if you have questions or would like more information about the study.

INDEPENDENT CONTACT

If you would like further information on the study from an independent contact, the C-GALL study office can put you in touch with the Chair of the Independent Steering Committee.

FURTHER INFORMATION AND CONTACT DETAILS

If you have any questions or would like any more information, please contact:

C-GALL Study office Centre for Healthcare Randomised Trials (CHaRT), Health Services Research Unit University of Aberdeen Health Sciences Building Foresterhill Aberdeen AB25 2ZD Tel: 01224 438089 Fax: 01224 438165 Email: cgall@abdn.ac.uk Web: https://w3.abdn.ac.uk/hsru/C-GALL	