

Patient agreement to investigation or treatment

Laparoscopic cholecystectomy

Authors: Cambridge Surgical Hepatobiliary and Pancreas Service

Brief description:

- This is an operation to remove the gall bladder using key-hole surgical techniques. The gall bladder is being removed because it is giving you pain due to gallstones. These small stones form in the gall bladder and can cause a range of problems including pain, jaundice, infection and pancreatitis. Gallstones are very common but do not always cause symptoms. Gallstones that are not causing trouble can usually be left alone.
- Here, we explain some of the aims, benefits, risks and alternatives to this procedure (operation/treatment). We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website: <http://www.addenbrookes.org.uk/consent>
- Remember, you can change your mind about having the procedure at any time.

For staff use:

Does the patient have any special requirements? (For example, requires an interpreter or other additional communication method)

.....

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About laparoscopic cholecystectomy

Your liver has many functions, one of which is to produce a substance called bile. This green liquid drains from the liver to the intestine via the bile duct. The gall bladder is a small reservoir attached to the side of the bile duct. The small amount of bile produced while we are not eating can be stored and concentrated here between meals. When we eat particularly fatty foods, the liver makes more bile and the gall bladder also contracts and empties this extra stored bile into the bile duct. It then travels to the intestine to mix with the food. Bile has many functions, one of which is to allow us to absorb fat. The gall bladder sits just under the liver, which is in the right upper part of the abdomen, just under the ribs.

We can manage without the gall bladder. Very rarely, patients notice that their bowels are a little looser than before the operation. You will be able to eat a normal diet after your operation, assuming that there is nothing else wrong with you.

Before your procedure

- Most patients attend a pre-admission clinic, when you will meet a senior member of the surgical staff who will explain all the options to you in detail.
- At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations. This is a good opportunity for you to ask us any questions about the procedure, but please feel free to discuss any concerns you might have at any time.
- You will be asked if you are taking any tablets or other types of medication - these might be ones prescribed by a doctor or bought over the counter in a pharmacy. It helps us if you bring with you details of anything you are taking (for example: bring the packaging with you).
- This procedure involves the use of a general anaesthetic. See below for further details about the types of anaesthesia we shall use.
- Most people who have this type of procedure will be able to go home a few hours after the operation. Sometimes we can predict whether you will need to stay for longer than usual - your doctor will discuss this with you before you decide to have the procedure.

During the procedure

- Before your procedure, you will be given the necessary anaesthetic - see below for details of this.
- Four small holes (about 1cm long each) are made in the abdominal wall (tummy). Through these, special long instruments are used to free up the gall bladder with its stones from underneath the liver and it is completely removed. This is all visualised on a TV screen by a miniature camera inserted through one of the four key-holes. During the procedure a small tube will usually be inserted into the bile duct allowing the surgeon to take an X-Ray. This is to make sure of the anatomy and also to exclude the presence of any bile duct stones which would require additional treatment.
- A soft plastic drainage tube (a drain) is occasionally placed in the abdomen via one of the small holes to allow fluid to drain away from the operation site for the first few hours after the operation.

How is this different from the traditional operation for gall bladder problems?

- The actual operation is the same. The only thing that differs is the way in which we get to the gall bladder to remove it. Traditionally, we make a small cut underneath the ribs (10-15 cm long). This takes longer to heal than the four little holes of key-hole surgery and the recovery is slower.

Is there a guarantee that key-hole surgery can be done?

- No, there is no guarantee that the operation can be completed by key-hole surgery. If there is some technical difficulty with removing the gall bladder then a traditional cut would be needed to remove it. The time in hospital would be a little longer (two to three days) and the recovery at home would be between six to eight weeks. The risk of having to convert to open surgery is small, about one to three per cent.

After the procedure

- You will wake up in the recovery room after your operation. You might have an oxygen mask on your face to help you breathe. You might also wake up feeling sleepy.
- After this procedure, most people will have a small, plastic tube in one of the veins of their arm. This might be attached to a bag of fluid (called a drip), which feeds your body with fluid until you are well enough to eat and drink by yourself.
- While you are in the recovery room, a nurse will check your pulse and blood pressure regularly. When you are well enough to be moved, you will be taken to a ward.
- Sometimes, people feel sick after an operation, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you more comfortable.
- Immediately after the operation there is some discomfort from the small cuts in the skin of the tummy but this is well controlled with simple pain-killers. All the wounds are closed with special dissolving stitches placed under the skin so that no stitches need to be removed.
- **Eating and drinking:** You can eat and drink normally as soon as you are fully awake following the operation.
- **Getting around and about:** When you wake up from the anaesthetic, you will be encouraged to move, sit up and out of bed, do some deep breathing exercises, cough and be generally active. This is for your well-being.
- **When you can leave hospital:** Most people who have had this type of procedure under **general anaesthetic** will be able to go home a few hours following surgery. The actual time that you stay in hospital will depend on your general health, how quickly you recover from the procedure and your doctor's opinion.
- **When you can resume normal activities including work:** It will then take 7 to 14 days to recover at home and most people are back to their normal activities within two to four weeks.

- **Special measures you need to take after the procedure:** You will be given more detailed information about any special measures you need to take after the procedure. You will also be given information about things to watch out for that might be early signs of problems (for example: infection).
- **Check-ups and results:** Before you leave hospital, you will be given a date to return to clinic for the results of your surgery. Any further treatment, if recommended, will be discussed with you then.

Intended benefits of the procedure

- Removing the gallstone will prevent the pain that you are getting from gallstones.

Who will perform my procedure?

- A team of surgeons who have the appropriate experience will carry out the procedure.

Alternative procedures that are available

- Unfortunately no alternative exists. The only successful treatment is to remove the gall bladder and gallstones completely. The results of this operation are very good and most patients can then return to eating a normal diet.

Serious or frequently occurring risks

Like all operations there are small risks. These are assessed on an individual basis depending upon patient's fitness and this should be discussed with your specialist prior to surgery. However, overall this is a very safe operation.

- There is a 1 in 400 risk of an injury to the bile duct, which will need further procedures or operations to repair the damage.
- There is a small risk of bleeding, infection and hernia formation following this procedure.
- In the event of a stone or stones being found in the bile duct (4% risk), further procedures will be required.
- There is a 1 to 3% risk of the key-hole operation being converted to an open traditional gallbladder operation and the chances of this happening are higher in complex cases and in those patients who have had previous surgery.
- Like any other operation, complications such as infection, bleeding, chest infections, adhesions, hernia, DVT and pulmonary embolus can occur.

Information and support

- You might be given some additional patient information before or after the procedure for example: leaflets that explain what to do after the procedure and what problems to look out for. If you have any questions or anxieties, please feel free to ask a member of the surgical team. They would be pleased to answer any queries you might have including the more detailed technical aspects of this procedure.
- If you have further questions please contact one of the HPB Specialist Nurse, on bleep number 154 225.

Your anaesthesia

There are different types of anaesthesia. The type chosen by your anaesthetist depends on the surgery you are undergoing as well as your health and fitness. Sometimes the different types of anaesthesia are used in combination.

General Anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation.

Before your operation

Before your operation your anaesthetist will visit you in the ward, although occasionally this will happen in a pre-anaesthetic assessment clinic. The anaesthetist who looks after you on the day of your operation is the one who is responsible for making the final decisions about your anaesthetic. He or she will need to understand about your general health, any medication that you are taking and any past health problems that you have had. Your anaesthetist will want to know whether or not you are a smoker, whether you have had any abnormal reactions to any of the drugs or if you have any allergies. They will also want to know about your teeth, whether you wear dentures, have caps or a plate. Your anaesthetist needs to know all these things so that he or she can assess how to look after you in this vital period. Your anaesthetist may examine your heart and lungs and may also prescribe medication that you will be given shortly before your operation, the pre-medication or 'pre-med'.

Pre-medication is the name given to medication (drugs) given to you some hours before your operation. These drugs may be given as tablets or injections. They relax you and may send you to sleep. They are not always given.

Do not worry if you do not have a pre-med, your anaesthetist has to take many factors into account in making this decision and will take account of your views on the topic if possible. Do not be worried about your anaesthetic. When your anaesthetist visits you before your operation, this is the time to ask all the questions that you may have, so that you can forget your fears and worries.

Before your operation you will usually be changed into a gown and wheeled to the operating suite into an anaesthetic room. This is an ante-room outside the theatre. The anaesthetist, his or her assistant and nurses are likely to be present. An intravenous line (drip) may be inserted. Monitoring devices may be attached to you, such as a blood pressure cuff or a pulse oximeter. A pulse oximeter is usually a little red light in a small box, which is taped to your finger. It shows how much oxygen you have in your blood and is one of the vital monitors that an anaesthetist uses during your operation to ensure that you remain in the best of health. You may be given some oxygen to breathe.

During your operation

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you in the correct level of unconsciousness for the period of the surgery. Your anaesthetist is constantly aware of your condition and trained to respond. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement. If you have any other medical conditions, your anaesthetist will know of these from your pre-operative assessment and be able to treat them during surgery.

After your operation

After your operation your anaesthetist continues to monitor your condition carefully. You will probably be transferred to a recovery ward where specially trained nurses, under the direction of anaesthetists, will look after you. Your anaesthetist and the recovery nurses will ensure that all the anaesthetic effects are reversed and that you are closely monitored as you return to full consciousness. You may be given some oxygen to breathe in the recovery area, and may find that intravenous drips have been inserted whilst you are unconscious in theatre and that these will be replacing fluids that you might require. You will be given medication for any pain that you might feel.

You are likely to feel drowsy and sleepy at this stage. Some patients feel sick, others may have a sore throat related to the insertion of the breathing tube during surgery. During this time it is important that you relax as much as you can, breathe deeply, do not be afraid to cough, and do not hesitate to ask the nursing staff for any pain relief, and about any queries you may have. You are likely to have hazy memories of this time and some patients experience vivid dreams. Once you are fully awake you will be returned to the ward, and if you are a day patient will be allowed to go to the waiting area to fully recover before you are accompanied home. Do not expect to feel completely normal immediately!

What are the risks of general anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on; whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or done in an emergency. Please discuss any pre-existing medical condition with your anaesthetist.

- Very common and common side effects (1 in 10 or 1 in 100 people)
Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, itching, aches, pains and backache, pain during injection of drugs, bruising and soreness, confusion or memory loss.
- Uncommon side effects and complications (1 in 1000 people)
Chest infection, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious during your operation).
- Rare or very rare complications (1 in 10,000 or 1 in 100,000)
Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.



We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas.

For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169

Help with this leaflet:



If you would like this information in another language, large print or audio format, please ask the department to contact Patient Information: 01223 216032 or patient.information@addenbrookes.nhs.uk

Polish

Jeżeli chciałbyś uzyskać te informacje w innym języku, w dużej czcionce lub w formacie audio, poproś pracownika oddziału o kontakt z biurem Informacji Pacjenta (Patient Information) pod numerem telefonu: 01223 216032 lub pod adresem patient.information@addenbrookes.nhs.uk

Portuguese

Se precisar desta informação noutra língua, em impressão de letras grandes ou formato áudio, por favor peça ao departamento que contacte a secção de Informação aos Doentes (Patient Information) pelo telefone 01223 216032 ou através do e-mail patient.information@addenbrookes.nhs.uk

Arabic

إذا كنت تود الحصول على هذه المعلومات بلغة أخرى، بالأحرف الكبيرة أو بشكل شريط صوتي، يمكنك أن تطلب من القسم الاتصال بمعلومات المريض على الرقم: 01223216032 أو عبر البريد الإلكتروني: patient.information@addenbrookes.nhs.uk

Cantonese

如您需以另一語言版本、特大字體或錄音形式索取本資料，請要求部門聯絡病人諮詢服務：電話 01223 216032，電郵地址 patient.information@addenbrookes.nhs.uk

Turkish

Eğer bu bilgileri başka bir dilde veya büyük baskılı veya sesli olarak isterseniz, lütfen bulunduğunuz bölümdeki görevlilere söyleyin Hasta Bilgilendirme servisini arasinlar: 01223 216032 veya patient.information@addenbrookes.nhs.uk

Urdu

اگر آپ کو یہ معلومات کسی دیگر زبان میں، بڑے الفاظ میں یا آڈیو طریقہ سے درکار ہوں تو برائے مہربانی اس شعبہ سے پیشینٹ انفارمیشن سے ذیل کے ذریعہ رابطہ کرنے کی درخواست کریں: patient.information@addenbrookes.nhs.uk یا 01223 216032

Bengali

আপনি যদি এই তথ্য অন্য কোন ভাষায়, বড় অক্ষরে বা অডিও রেকর্ডিং পেতে চান তাহলে 'প্যাশেন্ট ইনফরমেশান' এর সঙ্গে 01223 216032 নম্বরে ফোন করে বা patient.information@addenbrookes.nhs.uk ঠিকানায় ই-মেইল করে যোগাযোগ করার জন্য ডিপার্টমেন্টটিতে অনুরোধ জানান।

Document history

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Consent form 1

Patient agreement to investigation or treatment

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)
Responsible health professional/job title

Special requirements
 (For example, other language/other communication method)

Name of proposed procedure or course of treatment

Laparoscopic Cholecystectomy

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

I have explained the procedure to the patient. In particular, I have explained:

- The intended benefits of the procedure: Removing the gallstone will prevent the pain that you are getting from gallstones.....

Any serious or frequently occurring risks from the procedures including those specific to the patient Bleeding, infections, bile leak, hernia from port sites

- Any extra procedures that might become necessary during the procedure
- Blood transfusion Other procedure (please specify)

I have discussed what the treatment / procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

- The following information leaflet has been provided: Laparoscopic Cholecystectomy
 Version/Date/Ref: 4/ June 2010/ CF142.....

This procedure will involve:

- General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature:Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

- I have offered the patient information about the procedure but s/he has declined information.
-

Statement of the interpreter (if appropriate)

I have interpreted the information to the best of my ability, and in a way in which I believe s/he can understand:

Interpreter's signature..... Date:

Name (PRINT):.....

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will (eg Jehovah's Witness form)

Copy accepted by patient: yes / no (please circle)

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you.

You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person undertaking the procedure will, however, have appropriate experience.

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. **Yes** **No**

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** If you wish to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature:..... **Date:**

Name (PRINT):

If the patient is unable to sign but has indicated his/her consent, a witness should sign below. Young people may also like a parent to sign here (see guidance notes).

Witness' signature:..... **Date:**

Name (PRINT):

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature Date:

Name (PRINT): Job Title: