

Gastroenterology Department

WRITTEN INFORMATION AND CONSENT FORM

1. Consent form for endoscopic retrograde cholangiopancreatography (ERCP).

This document is for you, or whoever, represents you, to authorize the performance of this procedure. This means that you authorize us to perform it. You can withdraw this consent at any time. Signing it does not oblige you to undergo the procedure. Revoking this consent does not imply any adverse consequences that could compromise the quality of the care received. Before signing, please read carefully the following information. Please, let us know if you have any questions or need further information. We will be glad to assist you.

1.1. What is this about? What is this for? The ERCP is a useful procedure to study and treat problems of the bile and pancreatic ducts. The doctor passes a flexible tube with a lighted camera (endoscopy) through your mouth to find the bile and pancreatic ducts opening into the duodenum (papilla) and, then, he injects a dye (contrast) into the ducts. This allows the ducts to be seen on x rays, which are taken to see any injury and the need for treatment during the procedure.

1.2. How is this performed? During ERCP, patients lie on a comfortable position, face down or on their left side, and it takes about 30 or 60 minutes. Relaxation and the immobility of the duodenum are needed so patients receive a local anesthetic that is sprayed in the throat. An intravenous needle is also inserted into a vein to give the patient some sedatives (conscious sedation) and spasmolytic. Sometimes general anesthesia might be needed.

The patient will have a short-stay hospitalization to be properly prepared and to ensure the patient's safety after the procedure.

1.3. What effects will it have on you? ERCP tolerance is different for each patient. After this procedure, the patient may feel abdomen discomfort and nausea, which are usually managed with medications. Once the ERCP is finished, the patient is removed to a recovery room where he/she wait for detecting the possibility of any complication.

1.4. What are the benefits? ERCP is used when your doctor suspects that you may have any disease related to your bile or pancreatic ducts, such as gallstones (lithiasis) or narrowing.

Endoscopic treatments may be used during the procedure. The most frequent is the sphincterotomy, which consists on the enlargement of the opening of the common bile duct into the duodenum. The stones can then pass through. If there is a narrowing in any duct, the doctor may place a prosthesis, using a little tube made of plastic or metal, to allow the downward flow of bile into the bowel. Sometimes, a provisional nasobiliary drainage is recommended. This is a longer tube inserted through the nose. Around 10% of ERCP cannot be performed because of the impossibility of going into the bile duct. This could be due to anatomical defects (diverticula of the duodenum), previous surgeries involving the stomach or just because of special conditions affecting the area.

1.5. Other alternatives available in your situation: today, image techniques such as the MRI help us in the

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diagnosis of biliopancreatic diseases, so the ERCP is much more exact and usually helps with endoscopic treatments. Sometimes, we can use the x rays and the treatment through the skin, by pricking directly the liver (percutaneous transhepatic cholangiography). This technique has usually more risks and it is more uncomfortable, but both of them will be used if needed. In most cases, the therapeutic alternative is a surgery.

1.6. What are the risks? Any medical procedure has its risks. Risks do not usually occur and the procedure does not produce damage or undesirable side effects at all. However, this is not always the case. That is why you have to know all risks that this procedure may lead to.

1.6.1. The most frequent ones

- Most of them are slight and produced by no desirable reactions due to the medication given.
- Others are abdominal discomfort and bloating.
- Other minor complications are broken teeth, tongue bite, dislocated-jaw or no voice.

1.6.2. The most serious ones

- Inflammation of the pancreas (pancreatitis) due to its irritation or the infection of the bile (cholangitis). If sphincterotomy is performed, the patient might have bleeding and perforation or the break through the wall of the duodenum, but this is rare, or the obstruction of a big stone that cannot be taken out.
- Allergic reactions to the medicines, cardiopulmonary disorders and infections.
- If any of these risks show up, the patient will receive a specific treatment and will stay some more time in the hospital. In this case, the patient may need urgent treatment, even surgery.
- Some complications might lead to a fatal development. This is very rare but might occur.

1.6.3. The ones related to your own medical condition:

1.7. Special situations that must be taken into account: there are no outright contradictions to this surgery.

Related illnesses and your clinical situation make up the surgical risk. It has to be evaluated by the doctors and assume by the patient. In any case, this procedure may be inadvisable for patients suffering from illnesses such as diabetes, cardiopulmonary diseases, arterial hypertension, anemia, etc.

1.8. Other information of interest (to be taken into consideration by the healthcare professional)

1.9. Other issues we need your consent for

1.9.1. Sometimes, during the procedure, there are some unexpected findings. These might oblige to

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change the way for performing the procedure and to use variants of the same that were not initially planned.

1.9.2. Sometimes, it is necessary to take biological samples to better study your case. These samples might be saved and used later for research related to the disease you have. They will not be used directly for commercial purpose. If they were to be used for other purposes rather than the ones stated herein, your previous consent will be requested. If you do not consent for them to be used for research purposes, the samples will be destroyed once your case has been documented, according to the policies of our Healthcare Facility. In any case, your identity will be kept confidential at all times.

1.9.3. It may also be necessary to take images such as photographs or videos. They serve to better document the case. They can also be used for educational purposes or for the diffusion of scientific knowledge. In any case, they will be used only if you give your consent. Your identity will be kept confidential at all times.

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2. Consent form

- In case of patient's disability, the consent form must be obtained from the legal representative.
- In case of minor, when it is considered that he/she lacks sufficient maturity, the consent form must be obtained from the legal representative, although the minor should be always informed in accordance with his/her level of understanding and if he/she is over the age of 12, his/her opinion will be heard.
- If the patient is emancipated or is at least 16 years-old, he/she will be entitled to grant his/her own consent. However, in case of an action implying a severe risk, according to the judgment of the physician, legal representatives will also be informed and their opinion will be taken into account for the decision-making.

2.1. Patient's information and that of his/her legal representative (if required)

Patient's last and first names: ID/NIE:

Legal representative's last and first names: ID/NIE:

2.2. Professionals involved in the information and/or consent process

Last and first names: Date: Signature:

Last and first names: Date: Signature:

2.3. Consent

I, Mr/Mrs, do hereby certify that I agree with the procedure proposed to me. I have read and understood the information contained above. I was able to ask questions and address all my concerns. Therefore, I have consciously and freely decided to authorize the procedure. I am also aware that I can revoke my consent at any time I deem appropriate.

.....I DO....I DO NOT Authorize the performance of all appropriate actions, including modifications to the way of performing the procedure in order to avoid any danger or potential harm to my life or health, which could arise during the procedure.

.....I DO....I DO NOT Authorize the preservation and further use of any biological samples for research related to the disease I suffer.

.....I DO....I DO NOT Authorize that, in the event that the mentioned biological samples were to be used in different investigations, the researchers contact me in order to request my consent.

.....I DO....I DO NOT Authorize the use of the images for educational purposes or diffusion of scientific knowledge.

Location and date.....

PATIENT

Consent/Approval by

THE LEGAL REPRESENTATIVE

Signed by:

Signed by:

2.4. Rejection of the procedure

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I, Mr/Mrs, do not authorize the performance of this procedure. I do hereby assume the consequences that could arise related to my health or my life.

Location and date.....

PATIENT

Consent/Approval by
LEGAL REPRESENTATIVE

Signed by:

Signed by:

2.5.Revocation of consent

I, Mr/Mrs, have freely and consciously decided to revoke my consent for this procedure. I do hereby assume the consequences that could arise related to my health or my life.

Location and date.....

PATIENT

Consent/Approval by
LEGAL REPRESENTATIVE

Signed by:

Signed by: