



PATIENT INFORMED CONSENT FORM FOR ERCP (Endoscopic Retrograde Cholangio-pancreatography) EXAMINATION

Patient's Name - Surname:

Gender: ☐ F ☐ M

Patient ID No:

Date of Birth:

Father's Name:

ID NO:

Dear Patient / Patient Relative,

In order to clarify your pre-diagnosis/ diagnosis that based on the results of the tests and the assessments of your physician, additional investigations are required. This leaflet has been prepared to inform you about the examination method to be applied to you, and the potential risks of the application. This leaflet has been written to enable you to make an informed decision about agreeing to the procedure. It is essential that you read this leaflet thoroughly and carefully. Once you have read all the information, including the possibility of risks and complications, do not hesitate to ask any questions, which you may have regarding medical procedures, and sign this consent form once you are fully satisfied with the information provided by your physician.

1. PRE-DIAGNOSIS/DIAGNOSIS.....

General information about the ERCP?

ERCP ((Endoscopic Retrograde Cholangio-pancreatography) is a procedure that allows the endoscopist to examine the bile ducts, gallbladder and pancreas to detect any diseases related with bile ducts, gallbladder, pancreas or liver.

For ERCP, it is important to have clear images, so the stomach must be empty. You are required not to take any food or drink for 8 hours prior to the endoscopic examination. Before the endoscopic examination, your physician will ensure you understand the procedure and discuss any outstanding concerns or questions you may have. You will have a brief medical assessment with your physician. You will be asked some questions regarding your medical condition and any illnesses, medication or surgery you have had before. Therefore, it is the best to inform your doctor if you have any allergies to some medications. Also, if you have any current diseases, that may require special attention during the procedure, please inform your physician. Then, you will be escorted into the procedure room where the endoscopist and the nurses will introduce themselves and you will have the opportunity to ask any final questions. If you have any dentures you will be asked to remove them. Your throat will be sprayed with a local anesthetic before the test begins to numb your throat and prevent gagging. ERCP examination can be performed without being sedated. However, to make the procedure more comfortable, conscious sedation is the preferred method. Conscious sedation is a combination of the sedative drug and painkiller that administered into the cannula (tube) in your vein, which will make you relaxed and lightly drowsy but not unconscious. Since medication cause retrospective amnesia, you will remember almost nothing about the procedure.

2. PROPOSED EXAMINATION: ERCP ((Endoscopic Retrograde Cholangio-pancreatography)



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3. DRUG ADMINISTRATION: Not required ☐ Required ☐

4. ANAESTHESIA ADMINISTRATION : Not required ☐ Required ☐

If anaesthesia is required, the patient will be informed about the procedure and asked for consent relatively by the anaesthetist.

5. PROCEDURE

ERCP is performed to diagnose conditions of pancreas and bile ducts. ERCP is also used to treat those conditions. ERCP allows your physician to perform any necessary treatments, such as enlarging an obstructed bile duct and pancreatic duct by removing gallstones lodged in the bile duct, inserting special tubes for the treatment of bile and pancreatic duct strictures, inserting catheters into the bile duct to relieve an obstruction and maintain bile flow.

A thin, flexible fiber-optic endoscope is used by your doctor to examine the ducts that drain bile from your liver and gallbladder and digestive juices from the pancreas. Your throat is numbed with an anesthetic spray to relax your gag reflex and make it easier to insert the endoscope. Shortly before the test begins, you will be given medication intravenously to help you relax during the examination. Whilst you are sedated, your doctor will guide the lubricated tip of the endoscope into your mouth and gently move it down the throat into the esophagus, stomach, and duodenum until it reaches papilla where pancreatic ducts and bile ducts drain into the duodenum. The endoscope does not interfere with your breathing. A thin tube is then guided through the endoscope and contrast material is injected to outline the bile or pancreatic ducts. Several X-rays are taken. You will remain on your abdomen while the X-rays are developed. This will determine how the ECRP proceeds. Surgical instruments, called biopsy forceps or brushes, may be inserted through the endoscope to collect samples if it is required. If gallstones and/or duct obstructions are detected by X-rays, your physician will treat the conditions during the ERCP test. Sometimes it is required to make a small cut in the papilla where pancreatic ducts and bile ducts drain into the duodenum to help relieve an obstruction in the ducts. This is called a sphincterotomy, and it is painless. To do this, a specific device is guided through the endoscope to the papilla. In other cases, the doctor needs to insert a tube called a stent into an area where the bile duct is blocked to allow the bile to drain. With a low possibility, ERCP may be interrupted due to your medical condition or technical reasons. It will be processed at the second session, later at a time deemed appropriate by your doctor.

When the test is completed, the endoscope is slowly withdrawn.

6. RISKS OF THE PROPOSED PROCEDURE

Diagnostic and therapeutic endoscopic retrograde cholangiopancreatography (ERCP) is a well tolerated and safe procedure. Because of this fact, it is used instead of surgical approaches. However, it might rarely be associated with unforeseeable complications. ERCP is a safe procedure



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and serious complications are uncommon. If complications do occur, they are usually mild. These complications are rare and comprises adverse drug reactions (rarely life-threatening), acute pancreatitis, hemorrhage, cholangitis, and perforation, and sometimes life-threatening complications such as sepsis. The complications which can be classified as mild might occur in 10-20% of patients. 2-3 % of patients may experience severe complications which might require prolongation of hospitalization, intensive care and surgical approaches. Once a complication occurs, early recognition and prompt intervention will minimize the morbidity associated with that complication. The mortality risk is rare. It is important for you to recognize the early signs of possible complications and to contact your surgeon if you notice symptoms of severe abdominal pain, fever, chills, vomiting, or rectal bleeding.

7. WHAT HAPPENS AFTER THE PROCEDURE

Sedation given during the procedure will make you less alert and drowsy when you are moved to the recovery room after ERCP. You will be kept in the recovery room until most of the effects of the sedatives disappear. Your nurse will tell you when to resume your normal diet. Your physician will inform you of your test results on the day of the procedure. If biopsy was taken, biopsy results take several days to return, and you should contact with your surgeon to get these results. You will stay in the recovery room under observation for 2-24 hours and then you will be sent home. Your primary care doctor will be in contact with your endoscopist in order to plan what should be done later. Details of the results and any further treatment should be discussed with the doctor who recommended you have this procedure.

CONTENT AND CONSENT OF THE PROPOSED TREATMENT

- ✓ I have been verbally informed in detail of the proposed treatment. I have read the form regarding the medical procedure. All my questions have been answered adequately.
- ✓ In unexpected and emergency cases, I fully understand that if necessary, medical procedures, which have not been identified in this form, may be applied to me only to prevent serious damage to my health and for life saving purposes.
- ✓ I consent to the admittance of students/personnel or authorized equipment representatives to the procedure room for purposes of advancing medical education or obtaining important product information. I consent to any photographing or videotaping of the procedure for scientific purposes, provided that my identity is not revealed by the pictures or by descriptive texts accompanying them so that my physician may follow my therapy progression.
- ✓ photographs might be taken and videos might be recorded during the procedure and they might be used for scientific purposes.
- ✓ I have been informed of approximate cost of the medical treatment proposed.



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I....., have fully understood the content of this form. I hereby consent, in full consciousness, to the examination to be applied at the Near East University Hospital.

Signature:

Date:

Time:

If consent is taken from Legal Representative;

Degree of Blood Related Relative:

Reason of having a Legal Representative;

- ☐ Patient is unconscious ☐ Patient is younger than 18 ☐ Patient unable to make a decision
☐ Emergency

Witness' (if possible; someone that is not a hospital staff);

Name & Surname:

Signature:

Date:

Time:

Informant (Doctor's);

Name & Surname:

Signature:

Date:

Time:

Translator's (if needed);

Name-Surname:

Signature:

Date:

Time:

The patient informed consent form is signed personally by

- The competent patient who is 18 years of age or older
- The legal representative of the patient between 15-18 years of age.
- The legal representative of the patient who is unconscious, younger than 15 years of age, unable to make a decision and in emergency medical situations.