

Explanation for patients undergoing an ERCP (Endoscopic retrograde cholangiopancreatography)

Record of the explanation provided:

Date:

Dear Patient

Read the information **immediately** after receiving it. Complete the questionnaire, add the date and sign it, preferably on the day before the planned procedure. If you have any questions ask your doctor or the specialist carrying out the procedure (gastroenterologist).

You will be undergoing an ERCP (Endoscopic retrograde cholangiopancreatography – a procedure to allow the specialist to see into the biliary and pancreatic tract using a contrast medium). This package includes the following:

- an information brochure
- a questionnaire
- informed consent form

The Information Brochure:

In this brochure you will find information about the procedure as well as the reasons for the procedure and associated risks. Please read the brochure carefully.

Ask your doctor if you have any questions about the need or the urgency of the procedure, about other options, or about the risks of the examination. The physician who referred you for this procedure will be able to answer most of your questions. If necessary, the specialist (gastroenterologist) who will carry out the procedure can answer any additional questions (how the procedure is performed or other specific issues). If you would like to speak to the gastroenterologist please contact us or the physician who has referred you to us on time.

The questionnaire:

Please complete the questionnaire, which includes questions on bleeding disorders as well as the questions on medications, intolerances or allergies. If you take **blood thinners** (e.g. Sintrom, Marcoumar, Xarelto) or if you regularly take **Aspirin, Alcacyl, Tiatral, Plavix, Clopidogrel, Effient** etc. you need to speak to your physician at least one week before the procedure about stopping your medication if appropriate. Bring the completed questionnaire with you to the examination. Sign and date the questionnaire preferably one day before the procedure. If you have difficulties answering any of the questions contact us or your doctor in time.

Informed consent:

Read the informed consent carefully. You should also date and sign it at the latest **one day prior to the procedure**.

The information brochure is for your keeping.

The questionnaire and the informed consent will be kept at our practice

Information brochure: ERCP (Endoscopic retrograde cholangiopancreatography)

Why perform an ERCP?

You have been diagnosed with or are suspected of suffering from a condition of the bile ducts and/or the pancreas. An ERCP will allow a definite diagnosis and if necessary treatment of the condition.

What preparations are necessary for an ERCP?

Do **not take any food 6 hours** before the ERCP because the upper digestive tract must be clear of all food remains for the procedure. You **can drink fat-free liquids (no milk or coffee) up to 4 hours before** the procedure and stop taking your regular medication unless your doctor has explicitly told you otherwise.

Driving or operating machinery?

You will be given a sedative and pain medication. You will not be able to drive after receiving this medication. Do not drive your own car to the hospital. Please have somebody to accompany you after the procedure. For 12 hours after receiving the medication, your signature is not valid. This means that you should not sign any contracts during this time.

How is the ERCP performed?

The doctor will insert a canula for an infusion into your arm to administer the sedation and anaesthetic. In addition to the physician, there will be a trained nurse or assistant present at all times. The examination does not usually cause any pain. The examination is performed using a thin flexible „tube“ with a light and camera at the tip. This allows the physician to see through the mouth, digestive tract, stomach and duodenum as far as the entrance to the biliary system and the pancreas. A contrast medium will then be injected into the biliary tract via a fine catheter and x-rays will be taken. If pathological changes are diagnosed these can be treated during the procedure.

What additional steps can be taken during the ERCP?

The following procedures and treatments may be performed depending on the diagnosis: removal of gallstones from the bile ducts, removal of tissue from the biliary duct, widening of narrow passages in the biliary or pancreatic ducts, implant of a stent to bridge narrow passages and to allow the flow of bile or pancreatic secretions. For these procedures a papillotomy may be necessary, i.e. the cutting of the sphincter at the end of the biliary tract where it joins the small intestine. This is done using an electric cutter inserted via the endoscope. In some cases, a decision can only be made during a procedure as to what additional procedures may be necessary. The possible additional steps will be explained to you in detail before the procedure. The physician will decide during the procedure exactly what steps to take.

What risks are associated with ERCP?

The x-ray examination of the biliary and pancreatic tracts, papillotomy and other interventions are low-risk routine procedures. Although absolute care is taken complications may still occur which in rare cases can be life-threatening. The most important are inflammation of the pancreas (5-10%), bleeding (<5%), infection of the biliary tract (<5%), damage to the intestinal wall (perforation) (1-2%), impaired respiratory function, or cardiac disturbances following administration of the sedation. In rare cases, surgery or an extended period of hospitalization may be necessary. Furthermore, allergic reactions, damage to diseased teeth, or injury of the larynx can occur. Temporary hoarseness, difficulty swallowing, and uncomfortable bloating (caused by air in the stomach or small intestine) may occur following the ERCP.

What do I have to do following the procedure?

If your throat has been sprayed with a local anaesthetic you should not eat or drink for at least an hour. If you suffer from **stomach pain** or other symptoms (e. g. dizziness nausea, vomiting) or if you pass blood (usually in the form of a black thin stool), tell your doctor immediately or go directly to the emergency department of the nearest hospital.

Questions on the procedure?

If you have any further questions about the planned procedure ask your doctor. Before the procedure you can discuss any remaining issues with the specialist (gastroenterologist).

If you have any questions or problems you can contact the following physicians:

General practitioner		Tel:
Gastroenterologist	GastroZentrum Hirslanden	Tel: 044 387 39 55

Questionnaire

Questions about bleeding disorders:

	<i>yes</i>	<i>no</i>
1. Do you experience severe nosebleeds for no apparent reason?		
2. Do your gums bleed for no apparent reason (when cleaning your teeth)?		
3. Do you get bruise easily or suffer small bleeds on your skin without having injured yourself?		
4. Do you have the impression that you bleed longer after minor injuries (e.g. after shaving)?		
5. For women only: Do you have the impression that your periods are especially long , (>7 days) or that you have to change your tampons or sanitary protection very often ?		
6. Have you ever suffered long or severe bleeding during or after dental treatment ?		
7. Have you ever suffered long or severe bleeding during surgery ?(e.g. tonsillectomy, appendectomy, giving birth) ?		
8. Have you ever been given blood products during surgery?		
9. Does anyone in your family (parents, siblings, children, grandparents, uncles or aunts) suffer from a condition causing an increased tendency to bleed ?		

Questions about medications, allergies or other diseases:

1. Do you take coagulation inhibitors (blood thinners) (e.g. Sintrom, Marcoumar, Xarelto) or have you taken Aspirin, Alcacyl, Tiatral, Plavix, Clopidogrel, Effient etc. or 'flu' medication, pain killers or anti-rheumatic medication within the last 7 days? If yes, which?		
2. Are you allergic / hypersensitive (to any medication, latex, local anaesthetics, bandaids) ? If yes, which ones ?		
3. Do you suffer from a defective heart valve , or from heart or lung disease ? Do you carry a card for endocarditis-prophylaxis (green / red) ?		
4. Do you have a pacemaker / defibrillator or a metal implant ?		
5. Have you been diagnosed with malfunctioning kidneys (renal failure)?		
6. Are you diabetic ?		
7. For women: Are you pregnant or are likely to become pregnant ?		
8. Do you have any loose teeth, bridges or crowns or dental disease ?		

I, the person signing, have completed the questionnaire to the best of my knowledge.

Place, Date	Name of the patient	Signature of the patient
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Aufklärungsmaterialien empfohlen durch die Schweizerische Gesellschaft für Gastroenterologie SGGSSG, die Verbindung der Schweizer Ärztinnen und Ärzte FMH sowie der Stiftung Patientenschutz SPO.

Informed Consent

on the ERCP

(Endoscopic retrograde cholangiopancreatography – a procedure to allow the specialist to see into the biliary and pancreatic tract using a contrast medium)

Record of the oral explanation given by:

Date:

I, the person signing, am aware of the information brochure.

I have been informed by the physician about the reasons (indication) for the ERCP. I have understood the type, procedure, and risks of the ERCP. My questions have been answered to my satisfaction.

(check the appropriate box)

I agree to the ERCP	<i>Yes</i>	<i>No</i>
I agree to receive a sedative and/or painkiller for the procedure	<i>Yes</i>	<i>No</i>

	Name of the patient		Name of the physicians
Place, date	Signature of the patient	Place, date	Signature of the doctor

For patients who cannot provide their own consent:

	Legally responsible person		Name of the physician
Place, date	Signature of the legally responsible person	Place, date	Signature of the physician

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