

Patient information/declaration of consent for ERCP (imaging of the bile ducts and pancreas with a contrast substance)

Label

Declaration of informed consent

provided by:

Date:

Dear Patient,

Please be so kind as to read these documents as soon as you receive them. You should then complete the questionnaire and date and sign the documents, where possible on the day before the examination. If you have any questions, please contact your GP or the consultant performing the procedure (gastroenterologist).

You are to undergo a procedure known as ERCP (imaging of the bile ducts and pancreas with a contrast substance (dye)). We now enclose the following documents for this examination:

- an information sheet
- a questionnaire
- the declaration of consent form

Information sheet:

The information sheet contains details about the procedure used for the examination as well as its purpose and risks. Please make sure you read it through carefully.

If you have any further questions about the necessity and urgency of the examination, alternative procedures or the risks it involves, please contact your GP. The doctor who referred you for this procedure can answer most questions about it. Specific problems or queries about the technical details of the procedure can be answered as necessary by the consultant performing the examination (gastroenterologist). If you require this, please contact us or the doctor making the referral in good time.

Questionnaire:

Please be so kind as to complete the enclosed questionnaire in full to clarify your tendency to bleed and respond to the questions about any medication, intolerances or allergies you have. If you take anticoagulants to thin the blood (e.g. Sintrom, Marcoumar) or aspirin, Alcacyl, Tiatral, Plavix, Clopidogrel, etc. on a regular basis, please ask your GP whether you should stop such medication in good time (at least one week before the examination). Please bring the questionnaire with you to the examination. Where possible, make sure you sign and date the questionnaire one day before the examination. If you have any problems or are unclear about answers to your questions, please contact us or your GP in good time.

Declaration of consent:

Please also read the declaration of consent form through carefully. Here too, please make sure you sign and date the questionnaire at the latest on the day before the examination.

The information sheet is yours to keep, while the questionnaire and declaration of consent form are held on file by us with your medical records.

Documentation for informed consent recommended by the Swiss society for gastroenterology (SGGSSG), the FMH Swiss Medical Association and the Swiss organisation of patients (SPO Stiftung Patientenschutz)

Information sheet for ERCP

Why do I need ERCP?

You are suspected or have been found to be suffering from a disease affecting the bile ducts and/or pancreas. ERCP allows us to identify such complaints and treat them as necessary.

What preparations are necessary for ERCP?

Please do not eat any solid food from midnight onwards before the procedure as no particles of food should remain in the upper part of the digestive tract when ERCP is carried out. You can drink clear fluids not containing fat (i.e. not milk) up to 2 hours before the examination starts. Please do not take your regular medication unless specifically told to do so by your doctor.

Can I work/drive afterwards?

Sleep-inducing drugs and/or painkillers will be administered to you for the procedure. This means that you will not be able to drive after taking such drugs, so please do not come for the examination with your own vehicle. Make sure you are accompanied by another person. After you have taken these drugs, you should not sign any legally binding documents for 12 hours afterwards, i.e. you should not take out any contracts during this period.

What happens during ERCP?

Sedatives and sleep-inducing drugs are first of all administered during an infusion given via the arm. During the examination not only the doctor is present, but also a specially trained healthcare professional (nurse or medical assistant). The examination is not generally painful. The examination is carried out with the help of a thin, flexible tube with a light and a camera at the end of it. This allows the doctor to view the mouth, oesophagus (gullet), the stomach and the duodenum as far as the bile ducts and the pancreatic duct. A fine catheter is used to inject a contrast medium (dye) in the bile ducts, which are then X-rayed. If pathological changes are detected during examination, treatment takes place at the same time as the examination.

What additional procedures can be performed during ERCP?

Depending on the findings the following procedures and treatments will be carried out: removal of gallstones from the bile ducts, removal of tissue from the gall duct, widening of narrow points in the bile or pancreatic duct, insertion of a small tube to bridge narrow points and drain off secretions from the bile or pancreatic duct. For such treatment procedures it may be necessary to perform a papillotomy, i.e. incision of the sphincter at the end of the bile duct where it joins the small intestine. An electrical cutting instrument, which is inserted through the endoscope, is used for this purpose. In some cases it is only possible to decide which additional procedures are necessary in the course of the examination. Any additional procedures will be discussed with you in detail before the examination takes place. The doctor then decides during the examination which extra procedures he has discussed with you are necessary.

What risks are associated with ERCP?

X-ray examination of the bile or pancreatic duct, papillotomy and further treatments are all routine procedures involving low risk. Complications may however occur even with the greatest of care, possibly also becoming life-threatening in exceptional circumstances. They in particular include inflammation of the pancreas (5-10%), bleeding (<5%), infection of the bile ducts (<5%), injury to the intestinal wall (perforation) (1-2%), and respiratory or cardiovascular problems. Surgery or a lengthy stay in hospital may be necessary in rare cases. In addition, allergic reactions may occur, and possibly damage to the teeth if you already have dental defects, or injury to the larynx. After ERCP you may temporarily suffer from slight hoarseness, difficulty with swallowing or an unpleasant feeling of wind (due to air remaining in your stomach and small intestine).

What should I (not) do after the examination?

After a local anaesthetic has been sprayed on your throat, you should not eat or drink anything for at least an hour. Please contact your GP or go to Accident & Emergency at once if after ERCP you experience stomach ache or otherwise feel unwell (e.g. dizziness, nausea, vomiting) or notice bleeding from the anus (generally in the form of thin, black stools).

Any questions about the procedure?

If you have any further questions about the planned examination, please contact your GP. If you still aren't entirely clear about the procedure, get in touch with the consultant performing the procedure (gastroenterologist).

You can contact the following doctors about any queries or problems you might have:

GP		Tel:
Gastroenterologist		Tel:

Documentation for informed consent recommended by the Swiss society for gastroenterology (SGGSSG), the FMH Swiss Medical Association and the Swiss organisation of patients (SPO Stiftung Patientenschutz)



Questionnaire

Label

Questions about your tendency to bleed:

yes no

1. Do you have heavy nosebleeds for no apparent reason?		
2. Do your gums bleed for no apparent reason (when cleaning your teeth)?		
3. Do you have bruises (haematomas) or small bleeds on the skin without any apparent injury?		
4. Do you have the impression that you bleed a lot after minor injuries (e.g. when shaving)?		
5. Women: Do you have the impression that your period lasts a long time (>7 days) or do you constantly have to change tampons / sanitary towels?		
6. Have you ever experienced heavy or lengthy bleeding during or after dental treatment?		
7. Have you ever experienced heavy or lengthy bleeding during or after surgery (e.g. an operation to remove your tonsils / appendix or when giving birth)?		
8. Have you ever been given blood or blood products during surgery?		
9. Has anyone in your family (parents, siblings, children, grandparents, uncles, aunts) had a disease involving an increased tendency to bleed?		

Questions about medication, allergies, accompanying conditions:

1. Do you take anticoagulants to thin the blood (e.g. Sintrom, Marcoumar) or have you taken aspirin, Alcacyl, Tiatral, Plavix, Clopidogrel, etc. or medication for colds or flu, painkillers or rheumatism tablets in the last 7 days? If so, which ones?		
2. Do you have an allergy or hypersensitivity reaction (to medication, latex, local anaesthetics, sticking plaster)? If so, which?		
3. Do you have heart valve disease or a disease affecting the heart or lungs? Do you have a patient identification pass for the prevention of endocarditis (green / red)?		
4. Do you wear a cardiac pacemaker / defibrillator or metal implant?		
5. Are you known to suffer from any malfunction of the kidneys (kidney failure)?		
6. Are you diabetic?		
7. Women: Are you pregnant or could you be?		
8. Do you have loose teeth, a disease affecting the teeth or wear dentures?		

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

Place, date

Patient's
name

Patient's signature

Documentation for informed consent recommended by the Swiss society for gastroenterology (SGGSSG), the FMH Swiss Medical Association and the Swiss organisation of patients (SPO Stiftung Patientenschutz)

Declaration of consent

for ERCP
(imaging of the bile ducts and pancreas
with a contrast substance)

Label

Declaration of informed consent

provided by:

Date:

I, the undersigned, have taken note of the information sheet.

I have received detailed information from the physician about the reason (indication) for ERCP. I understand the nature of ERCP as well as the procedure and risks involved. My questions have been answered to my satisfaction.

(Mark with a cross as appropriate)

I consent to the performance of ERCP

Yes	No
-----	----

Patient's
name

Physician's name

Place, date ..
Patient's signature

Place, date ..
Physician's signature

For patients who are unable to give consent themselves:

Legal or authorised
representative

Physician's
name

.. Representative's signature

Place, date ..
Place, date

Physician's
signature

Documentation for informed consent recommended by the Swiss society for gastroenterology (SGGSSG), the FMH Swiss Medical Association and the Swiss organisation of patients (SPO Stiftung Patientenschutz)



..

Documentation for informed consent recommended by the Swiss society for gastroenterology (SGGSSG), the FMH Swiss Medical Association and the Swiss organisation of patients (SPO Stiftung Patientenschutz)

