

Clinic / Doctor:



Patient data:

englisch

Examination scheduled to take place on (date):

Dear patient,

your symptoms are caused by cardiac arrhythmia. In order to be able to determine the cause and the severity of your arrhythmia, your doctor has recommended an electrophysiology study (EPS).

The following text is intended to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you what the scheduled examination involves and inform you of any related risks. The doctor will answer all of your questions in order to reduce any fears or concerns you may have. You may then consent to the procedure suggested to you. Your doctor will provide you with a copy of the completed and signed form after the interview.

FUNCTION OF THE HEART

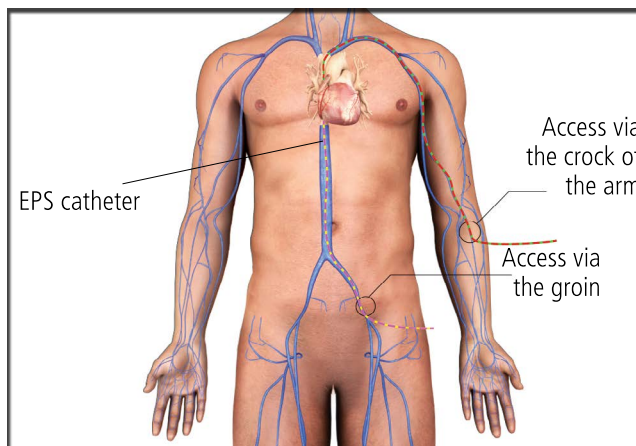
The heart consists of four cavities: two atria and two chambers. The heart's own electrical impulses maintain a regular heart-beat. These impulses are normally produced by special muscle cells in the right atrium, the so-called sinus node, and are then transmitted via the muscles of the atria. This leads to the atria contracting and pumping the blood into the cardiac chambers. A second group of muscle cells, the so-called AV node, then picks up the signal and transmits it via a special bundle of fibres to the cardiac chambers. The chambers contract shortly after the atria and, by doing so, pump the blood into the aorta and the lungs. In a healthy adult in a resting state, the heart normally beats at a rate of 70 times per minute.

If any malfunctions occur during the development or transmission of the electrical impulses, the heart will end up beating arrhythmically, which is then referred to as cardiac arrhythmia. The heart then beats too fast, too slowly or irregularly, and in some cases, the heartbeat may even stop intermittently. In extreme cases, this may lead to the body not being supplied with sufficient amounts of oxygen and to dizziness, tiredness, faintness or fainting as a result.

COURSE OF EPS

In order to determine the exact cause of your symptoms and to be able to decide what your further treatment should involve, your doctor has recommended an electrophysiology study. It involves the electrical impulses of the heart being measured directly at the heart. This allows for a much more precise measurement of the heart's impulses.

EPS is usually carried out under a local anaesthetic. If the procedure is to be carried out under a general anaesthetic in your particular case, you will receive a separate information sheet. If you so desire or if your doctor deems it necessary, you will receive a light sedative or sleep-inducing drug. In order to prevent formation of blood clots during the procedure, you may have an anticoagulant agent administered to you.



After your skin has been thoroughly disinfected and the area to be used for access by the doctor has been anaesthetised, the doctor, first of all, will puncture a suitable vein in your groin (in rare cases, in the crook of your arm, on your chest or neck).

Under X-ray guidance, he will then insert the catheter (a flexible plastic tube) through the blood vessels in your arm or leg and abdominal vessels all the way to your heart. It will often be necessary to insert additional catheters, for example using the other groin for access. If an examination of the left side of the heart is required, the doctor can also insert a catheter through an artery or through a small opening created by the catheter in the cardiac septum into the left chamber.

Every catheter has up to 20 metal contacts, through which the electrical impulses in various areas of the heart can be conducted and recorded. The doctor may then try to trigger your typical arrhythmia using either the catheter itself or medication. You may notice this as an uncomfortable irregular heartbeat or a drop in blood pressure accompanied by nausea and drowsiness.

In some cases, a contrast medium will be injected through the catheter in order to make the heart or the vessels visible under X-ray. While the contrast medium is being injected, you may

feel intense warmth for a short while. This is perfectly normal. After the procedure, the catheters will be removed and the accesses at the veins or the artery will be closed again.

POSSIBLE ADDITIONAL MEASURES

If atrial fibrillation occurs during the procedure, electrical cardioversion involving a brief power surge being sent through your heart may have to be carried out (cardioversion). If life-threatening cardiac arrhythmia is likely to occur during the procedure, defibrillation electrodes may be attached to your chest prior to the EPS procedure. In case of an emergency, the arrhythmia can then be stopped by administering a power surge. Cardioversion may be carried out under short-term general anaesthesia.

ALTERNATIVE METHODS

Alternative procedures to an electrophysiology study can be a long-term ECG or the implantation of a new recording device (loop recorder). However, they are not as precise as an EPS.

PROSPECTS OF SUCCESS

If the EPS shows that your heart is suffering from a conduction disturbance, various treatment options may be available. Catheter ablation can interrupt faulty conduction pathways. A pacemaker can be implanted in order to compensate a lack of electrical impulses, for instance in the sinus node. The EPS may sometimes serve to check the effectiveness of heart rhythm control with medication. In extreme and exceptional cases, the arrhythmia may get worse as a result of the examination.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Please follow the instructions of the doctor and of the nursing personnel closely. Unless specifically instructed otherwise, please adhere to the following guidelines:

Preparation:

Medication: It is important for you to inform your doctor of any medication you take on a regular basis (in particular any medication to treat cardiac arrhythmia, such as beta blockers, Verapamil or Digitalis, anticoagulant agents such as Aspirin® [ASS], Plavix®, Xarelto®, Pradaxa®, Eliquis®, Marcumar and metformin-containing antidiabetic medicines, so-called biguanides). This includes any over-the-counter medication and herbal remedies. Your doctor will let you know if and for how long you need to stop taking your medication.

Food, drink and smoking: Please stop smoking at least one day prior to the scheduled procedure. As a general rule, you may not eat anything anymore 6-8 hours prior to the procedure and not drink any juices with pulp, milk, broth or alcohol. You may imbibe clear fluids such as water or tea without milk or cream up until approx. 2 hours prior to the procedure.

Aftercare:

Please do not get up on your own after the procedure, as instructed, and leave the affected leg or arm outstretched and motionless until the insertion sheath has been removed. The puncture site will have pressure applied to it by the nursing personnel or have a special closing system applied to it and, if need be, a compression dressing.

Should you notice any **bleeding** at the puncture site, please apply pressure to the affected area and immediately inform the nursing personnel or the doctor.

In order to avoid post-procedure bleeding, it is necessary after **puncturing of the groin to stay in bed for several hours**. Excessive strain, heavy lifting or strong pressing should also be avoided for several days after the procedure.

If the procedure is **performed on an out-patient basis**, it is necessary for an adult to come and collect you. Please adhere to the instructions of your doctor regarding aftercare (such as bed rest) in order to promote full healing of the wound. Please make sure there will be an adult at home to monitor you for the period of time indicated by your doctor. You must not under any circumstances actively participate in road traffic for a period of **24 hours after the procedure** (not even as a pedestrian) nor participate in any risky activities. You should also refrain from taking any important personal or economic decisions during this period.

Please inform your doctor immediately or come to the clinic should you experience **bleeding, swelling, pain, intense reddening of the wound or secretion from the puncture site, numbness or paling of the affected limbs** or if you notice **pain in your chest, heart problems, shortness of breath, fever or chills**.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure is accompanied by certain risks**. These may sometimes require additional treatment or surgery and can sometimes even be **life-threatening** or lead to permanent damage – even after some time. Please understand that, for legal reasons, any possible risks associated with this procedure must be listed, even if some of these only occur in exceptional cases. During the interview, your doctor will inform you of any risks specific to your case. You may also choose to waive a detailed explanation. In that event, please pass over this section on risks.

Bruising (haematoma) often occurs around the puncture site. This may lead to firm, painful swelling. Most of the time, this will disappear even without treatment.

In some cases, the blood vessel will not close up properly at the puncture site, resulting in an **aneurysm of the vessel** (pseudoaneurysm). This can normally be treated effectively by applying a compression dressing or through an injection into the aneurysm (sclerotherapy). In rare cases, a connection will form between the artery and the vein (**fistula**), which will usually have to be closed surgically. **Impaired blood circulation** in the patient's leg or arm may occur if the punctured blood vessel was injured or has become blocked by a blood clot after the procedure. In exceptional cases, this may result in a loss of function of the affected limb, in extreme cases it may result in the patient losing the affected arm or leg. Sometimes **lymphatic obstruction** will lead to permanent swelling of the punctured limbs.

Damage to the skin, soft tissue or nerves - for instance through the puncturing, bruising, syringe abscess, disinfectants, a compression dressing or despite proper positioning - may occur. Numbness, paralysis and pain may then result. They are usually temporary. On rare occasions, these symptoms may persist even after treatment, or scars may remain.

During the procedure, **cardiac arrhythmia** may occur. It is usually of a temporary nature and harmless. Severe cardiac arrhythmia requiring treatment using medication or a power surge (defibrillation) occurs only in very rare cases.

In some cases, the moving forward of the catheter can lead to a **loop** forming. If it cannot be undone successfully, the catheter will have to be surgically removed.

Since during the procedure, anticoagulant agents will often have to be administered, the risk of **(post-procedure) bleeding**, particularly at the puncture site, but also in other areas of the body will be increased. In extreme cases, bleeding in the brain may occur, which can result in speech problems or paralyses. If

Heparin is administered as an anticoagulant agent, it may result in **severe coagulopathy** (HIT), leading to the formation of blood clots and obstruction of blood vessels.

Should **severe blood loss** occur, the use of donor blood/blood components (**transfusion**) may be required in exceptional cases. This can lead to **transmission of diseases**, albeit in very rare cases, such as hepatitis (causing dangerous inflammation of the liver), HIV in extremely rare cases (causing AIDS), BSE (causing a form of Creutzfeldt-Jakob disease) or also of other dangerous – even unknown – diseases.

Existing blood clots (**thromboses**) may become detached through the moving forward of the catheter and cause obstruction of a blood vessel (**embolism**). Blood clots can also form anew or travel to other organs, leading to blood vessel blockages there. Even despite immediate treatment, this may lead to permanent damage to the affected organ (e. g. **lung embolism, stroke** including permanent paralyses, **heart attack**).

Infections, for instance at the site where the catheter was inserted, involving a collection of pus (abscess), tissue death (necrosis) or scarring rarely occur. They will lead to swelling, redness, pain, warm skin and a temperature. In most cases, such infections can be treated successfully with antibiotics. In extreme cases, germs may be introduced into the bloodstream (bacteraemia), leading to life-threatening **blood poisoning** (toxaemia) or inflammation of the endocardium (endocarditis) as a result. Adequate intensive care will then be required. In extremely rare cases, an infection may result in the death of a patient despite proper treatment.

Important Questions for Outpatients

Wichtige Fragen für ambulante Eingriffe

Who will pick you up when you are discharged from the hospital/clinic/surgeon's practise? Wer wird Sie abholen, sobald Sie aus Klinik/Praxis entlassen werden?

Name and age of the person picking you up: [Name und Alter des Abholers]

Where can you be reached within the 24 hours after surgery?

Wo sind Sie in den nächsten 24 Stunden nach dem Eingriff erreichbar?

Street, house number, postcode, place: [Straße, Hausnummer, PLZ, Ort]

Telephone: [Telefonnummer]

Name and age of person looking after your: [Name und Alter der Aufsichtsperson]

Allergic reactions (intolerance symptoms), e.g. to anaesthesia, contrast media, sedatives or other medication involving skin rash, itching, swelling or nausea and coughing may occur. Severe reactions such as shortness of breath, spasms, tachycardia or circulatory shock are rare. Due to insufficient perfusion, temporary or permanent organ damage, e. g. brain damage, paralysis or kidney failure may occur even despite adequate intensive care.

If a contrast medium is administered for X-ray, patients already suffering from kidney disease may experience a **decrease in kidney function** or even suffer **kidney failure**; diabetics who are on biguanides such as metformin may experience dangerous **disturbances of the metabolism** (acidosis); patients with dysfunction of the thyroid gland may experience **hyperfunction of the thyroid**.

Injuries of the heart or large blood vessels through the catheter rarely occur. On rare occasions, the wall of the heart or one of the heart valves may be injured, leading to bleeding into the pericardial sac. Injuries may require surgery in order to be alleviated, or the pericardial sac will have to be punctured with a needle and the blood be aspirated from it.

The occurrence of **cardiac arrest** requiring resuscitation and sometimes leading to temporary or permanent organ damage e. g. brain damage, paralyses or kidney failure, is extremely rare.

Radiation exposure through X-ray is low. If a patient is pregnant, radiation may cause damage to the unborn child.

Who is your physician (the one whose care you are in/who referred you/family surgeon)? Wer ist Ihr überweisender Arzt / Hausarzt / weiter betreuender Arzt?

Name: [Name]

Street, house number: [Straße, Hausnummer]

postcode, place: [PLZ, Ort]

Telephone: [Telefonnummer]

Questions about Your Medical History

Please fill in the following questionnaire carefully before your information talk. **Please tick the applicable box!** It goes without saying that your information will be treated confidentially. The information you provide will help the physician to better assess the risks in your particular case, to advise you on the complications that could occur, and to take any steps needed to prevent complications and side effects.

Information about medications:

Do you regularly require blood thinning medications (anticoagulants) or have you taken any or have any been injected during the past 8 days? yes no

Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®.

Angaben zur Medikamenteneinnahme: Benötigen Sie regelmäßig blutgerinnungshemmende Mittel oder haben Sie in der letzten Zeit (bis vor 8 Tagen) welche eingenommen bzw. gespritzt? Aspirin® (ASS), Clopidogrel, Eliquis®, Heparin, Marcumar®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®.

Any other: _____
Sonstiges:

When did you take the last dose? _____
Wann war die letzte Einnahme?

Do you need regularly medications for high blood pressure or heart rhythm problems?

yes no

Amiodaron, Multaq®, Digitalis, Verapamil, Betablockers.

Benötigen Sie regelmäßig Medikamente gegen hohen Blutdruck oder Herzrhythmusstörungen? Amiodaron, Multaq®, Digitalis, Verapamil, Betablockers.

Any other: _____
Sonstiges:

When did you last take that medication? _____
Wann war die letzte Einnahme?

Do you take any other medications?

yes no

Werden andere Medikamente eingenommen?

If so, which ones: _____
Wenn ja, bitte auflisten:

(Please include non-prescription medications, herbal and other natural remedies, vitamins, etc.) (Auch rezeptfreie Medikamente, natürliche oder pflanzliche Heilmittel, Vitamine, etc.)

Do you have a pacemaker or a defibrillator?

yes no

Haben Sie einen Herzschrittmacher oder Defibrillator?

If yes, please bring your pacemaker ID card.
Wenn ja, bitte Herzschrittmacherausweis mitbringen.

Are you pregnant?

not certain yes no

Sind Sie schwanger?

nicht sicher

Do you smoke?

yes no

If so, what and how much daily: _____

Rauchen Sie? Wenn ja, was und wie viel täglich:

Do you drink alcohol regularly?

yes no

Trinken Sie regelmäßig Alkohol?

If so, what and how much: _____
Wenn ja, was und wie viel:

Do you have or have you ever had any of the following

diseases: Liegen oder lagen nachstehende Erkrankungen vor:

Heart, circulatory or blood vessel diseases? yes no

Heart attack, chest pain and/or tightness (angina pectoris), heart defect, irregular heart rhythm, inflammation of heart muscle, heart valve disease, shortness of breath while climbing stairs, heart surgery (possibly with insertion of an artificial heart valve, pacemaker, defibrillator), high blood pressure, low blood pressure, stroke, varicose veins, inflammation of a vein, thrombosis, embolism.

Herz-/Kreislauf-/Gefäß-Erkrankungen? Herzinfarkt, Angina pectoris (Schmerzen im Brustkorb, Brustenge), Herzfehler, Herzrhythmusstörungen, Herzmuskelerkrankung, Luftnot beim Treppensteigen, Herzoperation (ggf. mit Einsatz einer künstlichen Herzklappe, Herzschrittmacher, Defibrillator), hoher Blutdruck, niedriger Blutdruck, Schlaganfall, Krampfadern, Venenentzündung, Thrombose, Embolie.

Any other: _____
Sonstiges:

Diseases of the respiratory tract (breathing passages) or lungs? yes no

Asthma, chronic bronchitis, inflammation of the lungs, emphysema, sleep apnoea (intense snoring with breathing interruptions), vocal cord/diaphragm paralysis.

Erkrankung der Atemwege/Lungen? Asthma, chronische Bronchitis, Lungenentzündung, Lungenemphysem, Schlafapnoe (starkes Schnarchen mit Atemaussetzern), Stimmband-Zwerchfelllähmung.

Any other: _____
Sonstiges:

If certain answers are preselected, please correct them if anything has changed.)

