



Patient's name and address

Removal of Tissue/Cell Samples (Targeted Needle Biopsy) or Aspiration/Drainage of Fluid or an Abscess Using Imaging Guidance

Dear Patient, Dear Parents,

The purpose of this informed consent form is to help you prepare for the discussion. Please read it carefully before the discussion and complete the questionnaire carefully and completely. To make things easier, we are using "you" to address the patient in general in the following text, even if the examination is proposed for your child.

Which procedure is planned?

If a disease is present the nature and severity of which could not be adequately evaluated with the examinations performed up to the present, taking a tissue or fluid sample (biopsy) is recommended for more detailed diagnostics. The sample can be taken with various methods, e.g. by means of fine needle or punch biopsy.

If there are larger accumulations of fluids or pus, they are to be treated by suction or drainage.

The parts of the body or the organs for which the procedure is proposed are displayed with various imaging procedures, e.g. X-ray, computed tomography or ultrasound.

We will explain the procedure proposed for you, the various biopsy and imaging methods, their advantages and disadvantages, the different demands they place on the patient, risks and chances of success during the patient-doctor discussion.

In order to achieve images of an even better diagnostic value with the imaging technique used to guide the biopsy needle and depending on the clinical question being posed, a contrast medium is frequently administered to the patient either as a drink or by injection. If injection of the contrast medium is planned, a cannula is placed in an arm vein before beginning the procedure. In rare cases, the contrast medium is also injected directly into the accumulated fluid. During injection of the contrast medium, a sensation of warmth and tension can be experienced for a short period which then resolves by itself. To achieve a good image qual-

ity, you will possibly also receive instructions from the medical staff, e.g. not to move, to hold your breath, etc.

Are there alternative examination/treatment procedures?

If other examination/treatment methods (e.g. endoscopy, an operation) are of genuine consideration in your case, we will also explain their advantages and disadvantages, their different demands placed on the patient's body, risks and chances of success during the patient-doctor discussion.

How the procedure is performed

Generally, the procedure is carried out after administering local anaesthesia to the puncture site, in rare cases also under regional or general anaesthesia. If necessary, you will be counselled about the anaesthetic procedure, how it is prepared and performed and its associated risks in a separate patient-doctor discussion.

A hollow needle (biopsy cannula) or a drainage catheter is inserted through the skin and the underlying soft tissue and advanced to the area to be examined or treated. Insertion of and/or evaluation of the correct location of the needle/the catheter for removal/drainage of the tissue/fluid is guided by the proposed imaging procedure; at the same time, several images are recorded for the purpose of planning and documentation.

Subsequently, tissue or fluid is removed for microscopic (histologic) examination, or fluid or pus that has accumulated is suctioned or allowed to drain to the outside. Under certain circumstances, it may be necessary to obtain tissue/cell samples from various areas. When treating large cysts, abscesses or an excessive accumulation of fluid in body cavities the drainage catheter may have to remain in place for several days under certain circumstances.

If additional treatment measures are planned, like irrigation or injection of medications, you will be informed about them in a separate patient-doctor discussion.

The laboratory examination results of the tissue or fluid are usually available after a few days. If the results indicate that the disease is benign, further evaluation is usually unnecessary. If the results indicate that the disease is malignant, we will discuss further steps in the treatment with you in detail.

Even after the puncture site has healed completely, it can be necessary to perform a follow-up examination (computed tomography or magnetic resonance imaging, ultrasound). If a follow-up examination is required in your case, the doctor will notify you about it.

Risks and possible associated complications

Despite all the care taken, complications can arise which can even become life-threatening and require additional treatment/operations under certain circumstances. The frequency rates are only a general estimate and are intended for weighing the risks against each other. They are not the same as the definitions of side-effects stated in the package inserts of medications. Pre-existing/underlying diseases and individual unusual circumstances can significantly influence the rate of complications.

- In rare cases, a haematoma and skin/tissue/nerve damage can occur at the puncture site or due to measures that may be needed in conjunction with the procedure (e.g. injections, disinfection). Side-effects/complications which can be permanent under certain circumstances: Pain, inflammation, necrosis (death) of tissue, venous irritation/inflammation, scars and disorders of sensation or function, paralysis (e.g. of the extremities).
- If fluids or contents of the intestine escape into the abdominal cavity due to injury to an organ (e.g. the intestine or gall bladder), peritonitis (inflammation of the peritoneum, the membrane lining the abdominal wall and investing the organs) can occur. This rare but life-

threatening complication can necessitate an operation with an incision into the abdominal cavity. It can be required to place a temporary artificial anus.

- In very rare cases, removal of a punctured organ (e.g. the spleen, kidney) because of bleeding that cannot be stopped is necessary.
- Bleeding and rebleeding is rare. Relevant bleeding can necessitate an operation to stop it (haemostasis) and/or transfusion of blood. The risk of infection (e.g. with hepatitis, AIDS) due to the transfusion of foreign donor blood is extremely low, however. After the transfusion, it can be determined by a check-up whether such an infection has occurred contrary to expectations.
- Infection is rare. However, in extremely rare cases, life-threatening generalised blood poisoning (sepsis) due to the spread of pathogenic micro-organisms can occur, which necessitates inpatient medical treatment with antibiotics. Inflammation (e.g. of organs) and subsequently an abscess (accumulation of pus) can also occur and necessitate treatment with antibiotics.
- A proposed drainage of an abscess may require prophylactic treatment with medications (e.g. with antibiotics).
- If air escapes into the pleural cavity due to puncturing the lung or the pleura (pneumothorax), this can lead to difficulty breathing as well as chest pain. If the pneumothorax does not resolve by itself, a tube (drain) must be placed for approx. 2–3 days to discharge the air. In rare cases, bleeding into the lung with subsequent development of shock occurs, which can necessitate treatment on the intensive care unit.
- Dissemination of tumour cells after puncture is excluded almost completely but can occur in extremely rare cases.

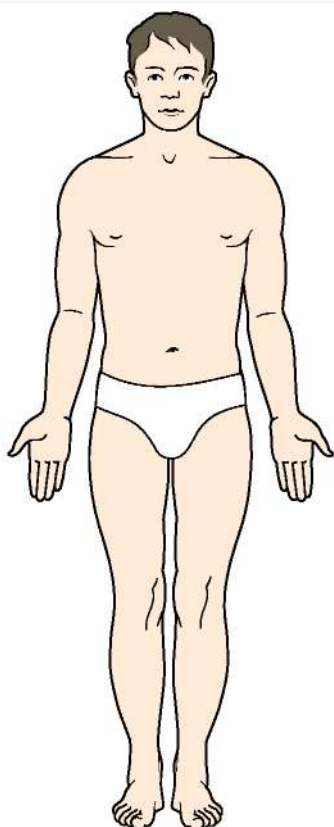


Fig. 1: Sketch for the doctor to mark the organ/body cavity or the biopsy extraction/withdrawal site

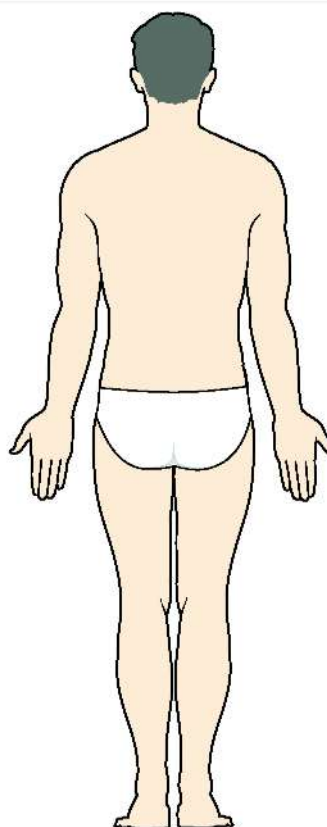


Fig. 2: Sketch for the doctor to mark the organ/body cavity or the biopsy extraction/withdrawal site

- **Allergy/hypersensitivity/incompatibility** (e.g. to the contrast medium, anaesthetic agents, sterilising agents, latex) can cause acute circulatory shock, necessitating intensive care. Severe damage (e.g. organ failure, brain damage, paralysis), which can be permanent under certain circumstances, is very rare. Mild allergic reactions can cause e.g. temporary swelling, itching, sneezing, skin rash, dizziness or vomiting. If you have known allergies or if you have had any side-effects/complications in association with previous examinations with contrast media, it may be necessary to give medications in preparation for an imaging technique which requires administration of a contrast agent (cortisone and/or antihistamines).
- In patients who have a predisposition for this condition, X-ray contrast media containing iodine can cause **over-activity of the thyroid gland** (hyperthyroidism), which can necessitate treatment with medications under certain circumstances. Furthermore, temporary **blood pressure fluctuations or disorders of the kidney function** can occur which go unnoticed in most cases. **Permanent kidney damage** which could necessitate dialysis is rare, even in cases in which kidney damage is already present.

You will be exposed to X-ray radiation in the proposed X-ray examination or computed tomography. However, the radiation dosage is so low that there is no risk of direct damage (e.g. to the skin or organs) by the radiation. Only the risk of occurrence of cancer after several years or decades is increased minimally. Therefore, the indication for this examination will only be issued by a doctor with the required qualification, and only if the chance of obtaining information clearly exceeds the low radiation risk. In particular, the doctor will thoroughly consider the indication for examinations in which an unborn child could be exposed to a higher dose of X-ray radiation if the patient is pregnant. If you have any further questions in this respect, please do not hesitate to ask us for further information.

What are the chances of success?

Microscopic examination of tissue or fluid frequently enables a more precise diagnosis. E.g. it can be determined whether a tumour is benign or malignant or the cause of inflammation or the causative pathogens (bacteria, viruses); however, these findings cannot be guaranteed. By withdrawing fluid that has accumulated due to disease (e.g. from body cavities, organs, joints, soft tissues), pain and other symptoms can be relieved. In many cases, suctioning/draining the fluid is all that is needed to treat and relieve the condition.

Despite employing careful techniques in marking the target area, it is possible that the needle will miss the target area.

In rare cases, the procedure has to be abandoned because of bleeding or technical problems. It may then be necessary to repeat it.

Despite the greatest care taken in removing the sample and examining it under the microscope, a malignant (early) finding can be overlooked, in particular if the suspicious finding in the imaging technique is very small and examination of the tissue or the fluid reveals normal findings.

Instructions

Before the procedure

Please provide any existing medical identification/records (e.g. Marcumar, allergy, pacemaker/implant, diabetes card

or X-ray card, etc.) and provide earlier X-ray, computed tomography/magnetic resonance imaging and ultrasound examination reports of the body region to be treated.

If you need to bring certain blood test results (e.g. creatinine, Quick's value, activated partial thromboplastin time, TSH levels, T₃ and T₄ if you have a known thyroid disease) for the procedure, your doctor will inform you about it.

Please list **all medications** that you are taking in the questionnaire (also herbal remedies and over-the-counter medications). The doctor treating you will then decide if and when these medications should be stopped or replaced by another medication. In particular, they include medications to thin the blood (e.g. Marcumar®, Aspirin®, Plavix® and new oral anticoagulants such as Eliquis®, Xarelto®, Lixiana®, Pradaxa® and similar) and, with patients suffering from diabetes, medications containing metformin.

If the procedure is planned under CT, MRI or X-ray guidance **with contrast**, we will provide you with detailed instructions with regard to preparing for the procedure.

On the day of the procedure

If the procedure is to be performed under local anaesthesia, please **do not eat anything for 2 hours** before the procedure; eat only a light meal before the period of fasting. Drink your usual amounts of fluid, but do not drink coffee, milk or alcoholic beverages.

After the procedure

Please follow the doctor's instructions carefully (e.g. with respect to bed rest) and leave the dressing in place.

If a contrast medium has been administered, please drink plenty of fluids (e.g. tea, mineral water, juice) so that the contrast medium will be excreted quickly.

If the procedure is performed on an **outpatient basis**, please remember that your reactions will be impaired for a certain period after receiving sedation, pain medication or an anaesthetic agent. Therefore, you have to be **picked up by an adult**. Due to the lingering effects of the medication, you may not actively participate in road traffic, may not perform any dangerous activities, may neither drink any alcohol nor smoke within the first 24 hours or the length of time stipulated by your doctor. You should also refrain from **making any important decisions**.

If you experience any symptoms (e.g. severe bleeding, pain, nausea, cardiocirculatory reactions, fever greater than 38 °C or chills), **immediately seek medical advice**, even if these symptoms only occur a few days after the procedure.

Place, date, time

Doctor

Questionnaire (patient history)

Please answer the following questions carefully and completely to aid us in avoiding all possible risks. Please mark boxes where applicable and underline or add text where appropriate. If necessary, do not hesitate to ask for our assistance in filling out the form.

Age: _____ years • Height: _____ cm • Weight: _____ kg

Gender: _____

n = no/y = yes

1. Are you taking any **medications** (e.g. anticoagulant medications [e.g. Marcumar®, Aspirin®], pain medications, antidiabetics [especially any medications containing metformin], cardiovascular agents, hormone preparations, sleeping pills or sedatives, anti-hypertensive medications)? n y
If yes, please indicate! _____
2. Do you have any **metabolic diseases** (e.g. diabetes, gout)? n y
If yes, please indicate! _____
3. Do you have or have you ever had any **cardiovascular diseases** (e.g. coronary heart disease, hypertension, cardiac arrhythmia, stroke, heart attack, angina pectoris, myocardial inflammation, heart valve defect)? n y
If yes, please indicate! _____
4. Do you have any **implants** (e.g. pacemaker, defibrillator, cardiac valve, stent, artificial joint, silicone, hydrogel, teeth, metal)? n y
If yes, please indicate! _____
5. Do you have or have you ever had any **diseases of the respiratory tract/lungs** (e.g. chronic bronchitis, pneumonia, bronchial asthma, hyperinflation, congenital malformation)? n y
If yes, please indicate! _____
6. Do you have or have you ever had any **diseases or malformation of the kidneys/urinary organs** (e.g. dysfunction of the kidneys, kidney stones, chronic urinary tract infection, nephritis/inflammation of the kidneys, congenital malformation [e.g. duplex kidney], bladder emptying disorder/delayed bladder emptying)? n y
If yes, please indicate! _____
7. Are you **dialysis-dependent**? n y
8. Do you have or have you ever had any **diseases of the blood** (e.g. anaemia, leukaemia, multiple myeloma, plasmacytoma)? n y
If yes, please indicate! _____
9. Do you have or have you ever had any **diseases of the thyroid gland** (e.g. overactivity of the thyroid gland, underactivity of the thyroid gland, goitre, Hashimoto's disease)? n y
If yes, please indicate! _____
10. Is an **examination, operation or radioactive iodine therapy** of the thyroid gland planned for the near future? n y
11. Do you have an **increased tendency to bleed** such as e.g. frequent nosebleeds/bleeding gums, bruises, rebleeding after operations? n y
12. Do you have any **skin diseases** (e.g. rash, psoriasis, tumour)? n y
If yes, please indicate! _____
13. Do you have any **allergies** (e.g. medications [e.g. antibiotics, Novalgin, paracetamol], anaesthetic agents, X-ray contrast media, latex, disinfectants, iodine, plaster, synthetic material)? n y
If yes, please indicate! _____
14. Do you have or have you ever had an **infectious disease** (e.g. hepatitis, HIV/AIDS, meningitis, tuberculosis)? n y
If yes, please indicate! _____
15. Have you undergone any **imaging procedures** in the last 10 years (e.g. X-ray examination, computed tomography, magnetic resonance imaging)? n y
If yes, please indicate! _____
If yes, in which part of the body (e.g. upper body, abdomen, spine, head, extremities)? _____
If yes, please indicate the name of the clinic/practice! _____
16. Have you ever undergone an examination with **contrast media**? n y
If yes, did any **complications** occur (e.g. rash, cardiocirculatory reactions, shock)? n y
If yes, please indicate! _____
17. Do you suffer from **claustrophobia** (fear of confined spaces)? n y

Additional questions for women

1. Could you possibly be **pregnant**? n y
2. Are you **breastfeeding**? n y

