

DISSOLVING OF BLOOD CLOTS (FIBRINOLYSIS) AUFLÖSUNG VON BLUTGERINNSELN (FIBRINOLYSE)

Information and medical history for patients for preparation of the required pre-procedure interview with the doctor

Clinic / Doctor:



Patient data:

englisch

Procedure scheduled to take place on (date):

Treatment with
 Streptokinase Anistreplase Staphylokinase
 Urokinase Tissue Plasminogen Activator
 Other: _____

Blood clot in the area of: _____

Dear patient,

you are to undergo treatment to dissolve one or more blood clots with medication (so-called fibrinolytic therapy).

This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you the advantages and disadvantages of the scheduled procedure compared with alternative methods available, and inform you of any risks specific to your case. 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.

REASONS FOR FIBRINOLYTIC THERAPY

Blood clots (so-called thromboses) can have various underlying causes, such as surgery, longer periods of immobilisation or bed rest, injuries or certain illnesses, e.g. varicose veins or a weakness of the heart.

The blood clots settle inside the blood vessels, cause their blockage (embolism) and can lead to severely impaired blood circulation and thus to a lack of oxygen and nutrition in the affected area of the body.

Thromboses in an artery can lead to, among other things, a heart attack, stroke or death of a limb. Blood clots in a vein can lead to life-threatening lung embolism.

For these reasons, prompt treatment can be required in cases where a blood clot has blocked a vessel. Often specific types of medication are used for this purpose, which are intended to lead to the blood clot dissolving (so-called fibrinolysis or fibrinolytic therapy). Their purpose is to destroy the main part of the blood clot, the so-called fibrin.

COURSE OF TREATMENT

Fibrinolysis can be carried out in two different ways. The doctor will discuss with you which of the two methods he would like to use in your case:

Administration of medication via a catheter (local treatment)

In this procedure, the medication is applied directly to the blood clot via a thin plastic tube, a so-called catheter, which is inserted into the blood vessel. The procedure is usually carried out under local anaesthesia.

Administration of medication via the circulatory system (systemic treatment)

The medication is injected through a vein and spreads throughout the entire circulatory system.

There are different types of medication available for fibrinolysis. In certain cases, it will also be necessary to administer anticoagulant agents in addition to the fibrinolytic therapy (such as Heparin or acetylsalicylic acid). Your doctor will discuss this with you.

ALTERNATIVE METHODS

Alternatively, weaker substances to prevent coagulation can also be used.

Blood clots inside a vessel can also be sucked out via a special type of catheter (aspiration thrombectomy).

Surgical procedures such as blood vessel enucleation or bypass surgery to bypass the blockage can also be used for treatment.

Your doctor will explain to you what the alternatives are and why he would recommend fibrinolytic therapy in your particular case.

PROSPECTS OF SUCCESS

The success of the treatment largely depends on the severity of the underlying disease. In most cases, the blood clots can be dissolved successfully with medication. However, the earlier treatment is undergone, the better.

In some cases, one or more blood clots may reform after some time even if the treatment was successful. Repeating the therapy or using another type of treatment method may then be necessary.

In order to treat the underlying causes of the thromboses formation, you may have various additional medications prescribed to you. Please take them conscientiously in order to ensure successful treatment.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Unless specifically instructed otherwise, please adhere to the following guidelines:

Preparation:

Medication: It is important to inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASS], Marcumar®, Plavix®, Eliquis®, Xarelto®, Pradaxa®, Lixiana®, Marcumar, etc.) or have taken irregularly over the course of the past eight days prior to the procedure. This includes any over-the-counter medication and herbal remedies. Your doctor will let you know which medication should be stopped for which period of time.

Aftercare:

Regular **check-ups** may be required after treatment. Please be very conscientious in keeping those appointments.

Please inform your doctor immediately or come to the clinic should you experience **fever, nausea, a general sense of feeling unwell or swelling at the injection site**. Since the medication used can lead to undesired bleeding, you should also see a doctor immediately or call the emergency services should you have **a severe headache, blood in your urine, bloody or black stool, cough up blood or suddenly develop bruises, experience disturbances of perception including vision disorders, or swelling of your legs or abdomen**.

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 and confirm your waiver with your signature in the final section of this form.

Medication used to dissolve blood clots increases the **risk of bleeding**. Spontaneous bleeding, such as inside the stomach, colon, bladder, brain, or bruising (haematomata) may occur more often. If the bleeding is severe, the medication may have to be reduced or stopped. The administration of a coagulant agent may then be required. Administering the medication via the circulatory system (systemic therapy) in particular can lead to **life-threatening complications** as a result of **bleeding in the brain** (permanent damage including paralyses, speech impairments or permanent disturbances of perception) or bleeding in other areas of the body.

Infections at the injection site, including syringe abscess, tissue death (necrosis) or vein inflammation (phlebitis), rarely occur. In most cases, such infections can be treated successfully with antibiotics. In extreme and exceptional cases, an infection that has spread beyond control can lead to **life-threatening blood poisoning** (toxaemia).

Bruising (haematomata) sometimes occurs at or around the puncture sites. This may lead to firm, painful swelling. Most of the time, it will disappear after a few days or weeks even without treatment. If not, surgical removal of the haematoma may become necessary.

Allergic reactions, for instance to the medication administered or to latex, can lead to skin rash, itching, swelling, nausea and coughing. Severe reactions, such as shortness of breath, spasms, tachycardia or **life-threatening circulatory shock** are rare. They may then result in permanent organ damage, such as brain damage, paralyses or kidney failure requiring dialysis.

Damage to the skin, soft tissue or nerves, - for instance through injections, bruising, syringe abscess, disinfectants - may occur. Numbness, paralysis and pain may then result. They are usually temporary. In some cases, permanent nerve damage, tissue death or scarring may occur.

Changes in the blood count or elevated liver enzymes may occur.

When a blood clot inside an artery is dissolved, the blood clot may be **flushed into the vessels supplying the hands and feet** as a result. If it is not possible to dissolve the blood clot with medication, fingers or toes may then die.

Different types of medication can reinforce or inhibit the effect of fibrinolytic therapy (e.g. pain medication or antirheumatics). If **Heparin is administered**, it may lead to a **severe immune response** (HIT) involving clotting of the platelets (thrombocytes) and obstruction of veins and of arteries.

Each type of fibrinolytic medication is accompanied by further **specific or very rare side effects**. You can read about them in the patient information leaflet inside the package of the medication. If you have any questions with regard to these, please consult your doctor.

Specific risks related to catheter treatment

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.

The moving forward of the catheter can result in **tears in the internal wall of a vessel (dissection)** accompanied by bleeding and constriction of the vessel or **complete obstruction of the vessel**. In such events, surgery may be required.

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.

Existing blood clots (**thromboses**) may become detached through the moving forward of the catheter and cause obstruction of a blood vessel (**embolism**). Even despite immediate treatment, this may lead to permanent damage to the affected organ (e. g. **lung embolism, stroke** including permanent paralyses, **heart attack**).

In rare cases, air may enter into the vein through the catheter (**air embolism**), leading to lung embolism or embolism in other organs.

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®, Efiect®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

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®, Efiect®, Brilique®, Ticlopidin, Xarelto®, Iscover®.

Any other: _____
Sonstiges:

When did you take the last dose? _____
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.)

Are you pregnant? not certain yes no
Sind Sie schwanger? nicht sicher

Did you give birth in the past two weeks? yes no
Hatten Sie innerhalb der letzten zwei Wochen eine Entbindung?

Have you ever suffered any bleeding (such as a gastrointestinal or brain haemorrhage)? yes no

Hatten Sie schon einmal eine Blutung (z. B. im Magen-Darm-Trakt oder im Gehirn)?

Have you received an injection, for instance vaccination, or have you had a puncture in the last week? yes no

Haben Sie in der letzten Woche eine Spritze, z.B. Impfung, erhalten oder wurde eine Punktion durchgeführt?

Did you suffer any injuries or undergo surgical treatment recently? yes no

Hatten Sie vor kurzem eine Verletzung oder einen operativen Eingriff?

Did you suffer a stroke in the past six months? yes no

Kam es in den letzten 6 Monaten zu einem Schlaganfall?

Have you ever had surgery on the brain? yes no

Wurden Sie schon einmal am Gehirn operiert?

Have you ever had a stomach endoscopy or a colonoscopy? yes no

Wurde bei Ihnen schon einmal eine Magen- oder Darmspiegelung durchgeführt?

Were there any complications? yes no
Ergaben sich dabei Komplikationen?

If so, which ones? _____
Wenn ja, welche?

Do you have or have you ever had any of the following diseases: Liegen oder lagen nachstehende Erkrankungen vor:

Do you have a malignant tumour (cancer)? yes no
Leiden Sie an einer Tumorerkrankung (Krebs)?

Have you ever had thrombosis (of the leg veins) or lung embolism? yes no

Hatten Sie schon einmal eine (Beinvenen-)Thrombose oder eine Lungenembolie?

Blood diseases / blood clotting disorders? yes no

Increased bleeding tendency (e.g. frequent nose bleeds, increased post-operative bleeding, increased bleeding from minor injuries or after dentist treatment, stronger or longer menstrual bleeding), tendency to bruise (frequent bruising possibly for no particular reason).

Bluterkrankung/Blutgerinnungsstörung? Erhöhte Blutungsneigung (z.B. häufiges Nasenbluten, verstärkte Nachblutung nach Operationen, bei kleinen Verletzungen oder Zahnarztbehandlung, verstärkte oder verlängerte Regelblutung), Neigung zu Blutergüssen (häufig blaue Flecken auch ohne besonderen Anlass).

Do you have any blood relatives with signs of blood disease / clotting disorders? yes no

Gibt es bei Blutsverwandten Hinweise auf Bluterkrankungen/Blutgerinnungsstörungen?

Allergies / Oversensitivity? yes no

Medications, foods, contrast media, iodine, sticking plaster, latex (e.g. rubber gloves, balloons), pollen (grass, trees), anaesthetics, metals (itching caused by metal spectacles frames, jewellery, jeans buttons).

Allergie/Überempfindlichkeit? Medikamente, Lebensmittel, Kontrastmittel, Jod, Pflaster, Latex (z.B. Gummihandschuhe, Luftballon), Pollen (Gräser, Bäume), Betäubungsmittel, Metalle (z. B. Juckreiz durch Metallbrillengestell, Modeschmuck oder Hosennieten).

Any other: _____
Sonstiges:

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, Brain aneurysm.

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

Any other: _____
Sonstiges:

Metabolic diseases? yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
Sonstiges:

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

Thyroid diseases? yes no

Underactive thyroid, Overactive thyroid, Basedow disease, Nodes, Thyroid swelling (goitre).
Schilddrüsenerkrankungen? Unterfunktion, Überfunktion, Basedowsche Krankheit, Knoten, Kropf.

Any other: _____
 Sonstiges:

Kidney diseases? yes no

kidney insufficiency, kidney inflammation.
Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierenentzündung.

Any other: _____
 Sonstiges:

Liver diseases? yes no

Liver inflammation, Elevated blood lipid levels.
Lebererkrankungen? Leberentzündung, erhöhte Blutfettwerte.

Any other: _____
 Sonstiges:

Gastrointestinal diseases? yes no

Stomach ulcer, inflammatory diseases of the bowel, Duodenal ulcer, Blood in the stool.
Magen-Darm-Erkrankungen? Magengeschwür, entzündliche Darmerkrankung, Zwölffingerdarmgeschwür, Blut im Stuhl.

Any other: _____
 Sonstiges:

Eye diseases? yes no

Diseases of the retina, Haemorrhages into the vitreous body, Eye operation.
Augenerkrankungen? Netzhauterkrankung, Glaskörperblutungen, Augenoperation.

Any other: _____
 Sonstiges:

Communicable (contagious) diseases? yes no

Hepatitis, tuberculosis, HIV.
Infektionskrankheiten? Hepatitis, Tuberkulose, HIV.

Any other: _____
 Sonstiges:

Any other acute or chronic diseases / illnesses? yes no

Nicht aufgeführte akute oder chronische Erkrankungen?

Please describe: _____
 Bitte kurz beschreiben:

Medical documentation for the informative interview

Ärztl. Dokumentation zum Aufklärungsgespräch

To be completed by the doctor Wird vom Arzt ausgefüllt

Über folgende Themen (z. B. mögliche Komplikationen, die sich aus den spezifischen Risiken beim Patienten ergeben können, nähere Informationen zu den Alternativmethoden, Erfolgsaussichten) habe ich den Patienten im Gespräch näher aufgeklärt:

Treatment with

- streptokinase anistreplase staphylokinase
 urokinase Tissue Plasminogen Activator
 Other: _____

Behandlung mit

- Streptokinase Anistreplase Staphylokinase
 Urokinase Gewebe-Plasminogenaktivator
 Sonstiges: _____

Blood clot in the area of: _____

Blutgerinnsel im Bereich: _____

Capability to give wilful consent:

Fähigkeit der eigenständigen Einwilligung:

- The patient is **capable of making a decision** on the recommended procedure on his/her own and giving his/her consent for the procedure.
 Der/Die Patient/in besitzt die Fähigkeit, eine **eigenständige Entscheidung** über die empfohlenen Maßnahme zu treffen und seine/ihre Einwilligung in den Eingriff zu erteilen.
- The patient is represented by a **custodian** with a custodian's card which states that he/she is also responsible for the patient's healthcare, or by a trusted person with a healthcare proxy. These persons are capable of making a decision in the best interest of the patient.
 Die Patientin/Der Patient wird von einem **Betreuer** mit einem die Gesundheitsorge umfassenden Betreuerausweis oder einer Vertrauensperson mit einer Vorsorgevollmacht vertreten. Diese sind in der Lage, eine Entscheidung im Sinne des Patienten zu treffen.
- Custodian's card healthcare proxy advance healthcare directive has been submitted.
 Betreuerausweis Vorsorgevollmacht Patientenverfügung liegt vor.

Place, date, time [Ort, Datum, Uhrzeit]

Doctor's signature [Unterschrift der Ärztin/des Arztes]

Patient's refusal Ablehnung

The doctor _____ has provided me with detailed information regarding the procedure at hand and has also pointed out the disadvantages of rejecting it. I have understood the information provided to me and reject the procedure suggested to me.

Die Ärztin/der Arzt hat mich umfassend über die vorgeschlagene Maßnahme und über die sich aus meiner Ablehnung ergebenden Nachteile aufgeklärt. Ich habe die diesbezügliche Aufklärung verstanden und lehne die mir vorgeschlagene Maßnahme ab.

Place, date, time [Ort, Datum, Uhrzeit]

Refusal of patient / legal guardian / witness if applicable
 [Ablehnung Patientin / Patient / Betreuer / ggf. des Zeugen]

DECLARATION OF CONSENT

Please tick the appropriate boxes and confirm your statement with your signature below:

- I hereby confirm that I have understood all sections of this form.** I have read the entire form (5 pages). During the pre-procedure interview with the doctor _____, I received detailed information regarding the course of the scheduled procedure, the risks, complications and side effects associated with it as they apply to my particular case as well as the advantages and disadvantages of any alternative methods. **Ich bestätige hiermit, dass ich alle Bestandteile der Patientenaufklärung verstanden habe.** Diesen Aufklärungsbogen (5 Seiten) habe ich vollständig gelesen. Im Aufklärungsgespräch mit der Ärztin/dem Arzt wurde ich über den Ablauf der geplanten Maßnahme, deren Risiken, Komplikationen und Nebenwirkungen in meinem speziellen Fall und über die Vor- und Nachteile der Alternativmethoden umfassend informiert.
- I deliberately refrain from obtaining a more detailed explanation.** However, I hereby confirm that the doctor _____ instructed me regarding the necessity of the procedure, its type and scope as well as the fact that all medical procedures are accompanied by certain risks. **Ich verzichte bewusst auf eine ausführliche Aufklärung.** Ich bestätige hiermit allerdings, dass ich von der Ärztin/dem Arzt über die Erforderlichkeit der Maßnahme, deren Art und Umfang sowie über den Umstand, dass alle medizinischen Maßnahmen Risiken bergen, informiert wurde.

I hereby confirm that I do not have any additional questions and do not need more time for consideration. I consent to the procedure proposed. My consent also applies to any necessary additional measures. I have answered the questions regarding my medical history (anamnesis) fully to the best of my knowledge.

Ich versichere, dass ich keine weiteren Fragen habe und keine zusätzliche Bedenkzeit benötige. Ich stimme der vorgeschlagenen Maßnahme zu. Meine Einwilligung bezieht sich auch auf alle notwendigen Neben- und Folgemaßnahmen. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

I confirm that I am capable of following the instructions given to me by my doctor.

Ich versichere, dass ich in der Lage bin, die ärztlichen Verhaltenshinweise zu befolgen.

- I agree that my copy of this explanatory form may be sent to the following e-mail address: Ich bin damit einverstanden, dass meine Kopie dieses Aufklärungsbogens an folgende E-Mail-Adresse gesendet wird:

e-mail address [E-Mail-Adresse]

Place, Date, Time [Ort, Datum, Uhrzeit]

Signature of the patient / legal guardian(s) [Unterschrift Patientin / Patient / Betreuer]

Copy/Kopie:

- received/erhalten
 waived/verzichtet

Signature Copy received/waived
 Kopieerhalt/-verzichtet