

Clinic / Doctor:



Patient data:

englisch

- Facet joint injection
 sacroiliac joint injection
 PRT
 without contrast media
 with contrast media

on (date): _____
 under X-ray ultrasound CT MRI guidance

Dear patient,

your doctor has recommended that you undergo a nerve root infiltration/facet joint injection/sacroiliac joint injection procedure. This form will serve to prepare you for your pre-procedure interview with the doctor. During the interview, the doctor will explain to you what the scheduled treatment 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.

CAUSE OF SYMPTOMS

Oftentimes, it is a sign of degeneration or a spinal disc herniation which causes back pain. Among other things, this may lead to a reduction of the size of the openings in the spinal column through which the spinal nerves exit (neuroforaminal narrowing). This narrowing may lead to the exiting nerve being irritated, subsequently causing you pain. Nerve root infiltration can be used to directly treat such a compressed nerve with medication; this procedure is referred to as periradicular nerve infiltration.

Degeneration of the small joints between the vertebrae or the sacroiliac joint gaps (joint between the sacrum and the ilium) can also lead to pain. The actual mechanism behind this is not yet fully understood. It is assumed that these joints or joint capsules are also supplied by a fine web of nerves. Therefore, pathological changes, such as signs of wear, may occur in this area as well, causing pain. Facet joint or sacroiliac joint injections are an attempt at treating those joints.

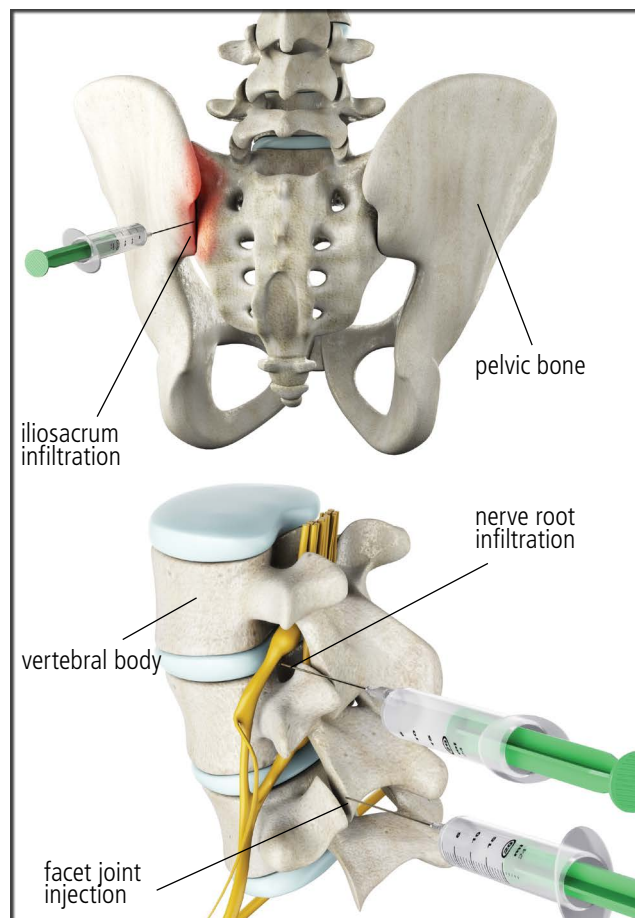
COURSE OF TREATMENT

First of all, you will be positioned on the examination table. Depending on the access path, you may be positioned on your stomach, your side or your back. The injection point is usually determined using imaging methods (ultrasound, CT, MRI, X-ray). The puncture site is marked on the skin and the skin surface is disinfected. Then, a thin hollow needle (cannula) is inserted under visual guidance all the way to the nerve root, the sacroiliac joint or the facet joint. Since the tip of the needle is moved very closely to the nerve root or the facet joint, you may feel pain at this point. They may be similar in quality to the type of pain that led you to see your doctor in the first place. Please let your doctor know if you experience any pain during the infiltration procedure.

Depending on the puncture site, a few millilitres of contrast media may have to be injected in order to be able to control the direction in which the injected medication spreads. Once the needle tip has been positioned in the right place, a few millilitres of the medication or combination medication are injected. Then,

the cannula is removed and the puncture site is covered with an adhesive bandage.

The time frame for this treatment can vary from a few minutes to over an hour. It is influenced, among other things, by the region to be treated, the procedure used or the number of nerve roots to be treated.



Both nerve root infiltration or facet joint and sacroiliac joint injection can be used as diagnostic or therapeutic measures.

Often the symptoms are not specific enough, nor can the exact nerve or joint which is causing them be allocated precisely. By injecting a local anaesthetic with a short duration of action, the doctor can try to locate the affected area (= diagnostic infiltration). This diagnostic infiltration can lead to a short period where the pain is gone or reduced. However, it is to be expected that the pain will return once the effects of the local anaesthetic wear off. This would be an indication for the doctor that the nerve root or joint treated is part of the problem causing your symptoms.

Diagnostic infiltration may have to be applied to different areas within a short period of time in order to identify exactly which area is affected. This is particularly important if an operation may be required in the long-term. Once the area causing your symptoms has been identified, this area can then also be infiltrated therapeutically. For this purpose, a few millilitres of a combination of local anaesthetic and anti-inflammatory medication are injected. Even though cortisone would be suitable for treatment of this type and causes little side-effects, its use in this context has not yet been officially approved.

ALTERNATIVE METHODS

Nerve root infiltration, facet joint injection or sacroiliac joint injection are useful when conservative methods such as physiotherapy or medication are not sufficient, if an operation is not indicated or if it can be delayed for some time.

PROSPECTS OF SUCCESS

The goal of this treatment method is to keep the nerves involved from sending any pain signals. Around half of the patients treated are permanently pain-free after treatment. Two thirds can at least count on a temporary reduction of their symptoms. The procedure can then be repeated to a limited extent within a relatively short period of time (approx. 2 weeks).

Any signs of degeneration, such as a narrowing of the nerve openings caused by degeneration of the spine or degeneration of the facet joints or sacroiliac joints, are not influenced in any way by the infiltration. However, it could be established that surgical intervention can be delayed through nerve root infiltration or even be made redundant.

Severe degeneration of the spine or pelvis may lead to the access path being blocked in part or entirely. In such an event, it may be impossible to carry out the infiltration procedure.

DIRECTIONS FOR PREPARATION AND AFTERCARE

Please bring any previous X-ray or CT images or findings with you.

Preparation:

Medication: It is important for you to inform your doctor of any medication you take or inject on a regular basis (in particular any anticoagulant agents such as Aspirin® [ASA], Marcumar®, Heparin, Plavix®) 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 if and for how long you need to stop taking your medication.

Aftercare:

Nerve function may be temporarily impaired through the effects of the injected medications, leading to muscles supplied by these nerves losing their strength. This may then result in **temporary paralysis**.

Lying flat on the examination table may lead to dizziness once you get up. Please rise from the table slowly and remain seated for a moment before you finally get up. Should you be uncertain

whether or not you are able to get up on your own, please ask for assistance.

If the procedure is performed **on an out-patient basis**, it is necessary for an adult to come and collect you. Your reaction capacity may be impaired through the injection of analgesics or you may experience temporary paralysis or lessened muscle strength. You must therefore not 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.

If you suffer from **diabetes**, please check your **blood sugar levels** continuously in order to prevent any fluctuations in blood sugar levels.

Please inform your doctor immediately or come to the clinic should you experience symptoms such as **rash, shortness of breath, tachycardia, cold sweat, headache, stiffness of the neck, fever, back pains, chills, paraesthesia** after the procedure. These symptoms require immediate medical attention. They may occur even days after the procedure.

RISKS, POSSIBLE COMPLICATIONS AND SIDE EFFECTS

It is well known that **any medical procedure is accompanied by certain risks**. If complications occur, they may sometimes require additional treatment or surgery and, in extreme cases, 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.

Allergic reactions (intolerance symptoms), for instance to contrast media, anaesthetics or other medication, rarely occur. Skin rash, itching, swelling or nausea and coughing may then occur as a result. They normally disappear without treatment. Severe reactions such as shortness of breath, spasms, tachycardia or **life-threatening** 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.

Especially in the event of repeated or multiple injections of cortisone-containing medication, systemic side effects of the medication such as weight gain, wateriness (oedema) or lens opacification (cataract) cannot be excluded. Women may experience menstrual irregularities, in cases with pre-existing diabetes a **blood sugar imbalance** may occur.

The insertion of the cannula can lead to injuries of neighbouring areas, the nerve root itself or of the treated joint. If vessels are injured, **bleeding** or bruising may occur. If the bleeding is too strong or cannot be controlled, surgical intervention may be required to stop the bleeding. 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, such as hepatitis in very rare cases (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.

If the anaesthetic accidentally ends up in the blood stream, **convulsive seizures, heart/circulatory problems** and even **loss of consciousness** and **respiratory failure** may occur. Immediate intensive medical care will then be required to prevent permanent brain damage.

Accidental **nerve damage**, a haematoma or an infection may lead to temporary or **permanent nerve paralysis** (in extreme cases even to **paraplegia**). Should the spinal canal be injured, this may result in a **loss of cerebrospinal fluid** (Liquor). If a local anaesthetic ends up in the spinal canal as a result of the injury, temporary paralysis of the lower half of the body may possibly occur.

Injections into the joint capsule (in facet joint or sacroiliac joint injection) may result in a **joint capsule tear**. This can lead to pain, increased risk of infection and a speeding-up of the degeneration process.

Infections at the puncture site, including syringe abscess or tissue death (necrosis), 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, an abscess may require surgical intervention or germs may be introduced into the bloodstream, leading to dangerous blood poisoning (toxaemia) or inflammation of the endocardium (endocarditis) as a result.

Injections in the area of the thoracic spine may result in **injury of the lining around the lungs** (pleura) in very rare cases. If this results in air entering into the chest, it may push aside the lungs, impairing lung function – even permanently (pneumothorax). Chest pains, coughing, restlessness, sweating, increased heart rate and shortness of breath may then occur. The air will then have to be removed through puncture or insertion of a drain.

Any **radiation exposure** is kept to a minimum during an infiltration procedure under CT or X-ray guidance. However, reliable data regarding the long-term effects is currently not available. If a patient is pregnant, radiation may cause damage to the unborn child.

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 you: [Name und Alter der Aufsichtsperson]

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.

Gender: M / F, **age:** _____ **years, weight:** _____ **kg, height:** _____ **cm**
Geschlecht: m / w, **Alter:** _____ **Jahre, Gewicht:** _____ **kg, Größe:** _____ **cm**

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), Brilique®, Clopidogrel, Efient®, Eliquis®, Heparin, Marcoumar®, Iscover®, 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), Brilique®, Clopidogrel, Efient®, Eliquis®, Heparin, Marcoumar®, Iscover®, Plavix®, Pradaxa®, Ticlopidin, Xarelto®.

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

Have you ever had an infiltration of the nerve roots /facet joints/sacroiliac joints? yes no

Haben Sie schon einmal eine Wurzel-/Facettengelenks-/Iliosakralfugeninfiltration erhalten?

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

If so, what complications? _____
 Wenn ja, welche?

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

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?

Blood clot (thrombus) / blood vessel occlusion (embolism)? yes no

Blutgerinnsel (Thrombose)/Gefäßverschluss (Embolie)?

Do you have a malignant tumour (cancer)? yes no

Leiden Sie an einer Tumorerkrankung (Krebs)?

If so, which ones: _____
 Wenn ja, an welcher?

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:

Metabolic diseases? yes no

Diabetes (sugar sickness), Gout.

Stoffwechsel-Erkrankungen? Diabetes (Zuckerkrankheit), Gicht.

Any other: _____
 Sonstiges:

Kidney diseases? yes no

kidney insufficiency, kidney inflammation.

Nierenerkrankungen? Nierenfunktionsstörung (Niereninsuffizienz), Nierentzündung.

Any other: _____
 Sonstiges:

Gastrointestinal diseases? yes no

Stricture in digestive tract, stomach ulcer, heartburn, Duodenal ulcer.

Magen-Darm-Erkrankungen? Engstelle im Verdauungstrakt, Magengeschwür, Sodbrennen, Zwölffingerdarmgeschwür.

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:

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

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:

I have proposed:

Vorgeschlagen habe ich:

Facet joint injection sacroiliac joint injection PRT
 without contrast media with contrast media
 under X-ray ultrasound CT MRI guidance

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. 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. Die Fragen zu meiner Krankengeschichte (Anamnese) habe ich nach bestem Wissen vollständig beantwortet.

My consent also applies to any necessary additional measures as well as to any required changes or additions to the procedure. Meine Einwilligung bezieht sich auch auf alle notwendigen Neben- und Folgemaßnahmen, sowie auf erforderliche Änderungen oder Erweiterungen des Maßnahme.

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