

Patient:

Treating physician:

DOB:

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1. General information

Dear patient,

It is important that prior to the treatment you are well informed. Therefore please take your time reading the following information. If something is not clear, or if you would like to know more details about the procedure, possible complications and risks, specifics for your individual case or any other issues, please do not hesitate to ask. We will gladly answer all your questions!

You do not have to fast – you can eat a regular breakfast. But do not eat for at least 3 hours before the scheduled procedure. Exception: Patients with allergies have to stop eating the evening before. Drinking water is allowed and recommended.

You can and should take your regular medications – if needed bring the necessary medicines for your stay. **Exception: Blood thinners or anti-coagulation medicines!**

If you are taking Metformin (Glucofage®, Siofor®, Metformin IR etc.) you must discontinue it three days before the angiography takes place. Please ask your general practitioner or diabetologist what other medication you can take for that period. Three days after the angiography it is safe to start taking Metformin again. **If Metformin is not stopped, we cannot perform the angiography.**

For the observation time following the procedure you can bring something to read. For your convenience there will be a television in your room. We have our own cafeteria for family members accompanying you and a variety of drinks will be provided.

2. Information about the angiography

Based on your previous examinations/medical evaluation it is necessary to perform the stem cell transplant via an angiography in order to place the stem cells accurately in the target organ.

An angiography is an X-ray examination to visualize blood vessels by injecting contrast dye.

The entire procedure lasts about 30 to 60 minutes. Normally the procedure is not painful and is done under local anesthesia. If you want to we can give you a sedative prior to the procedure.

3. Course of the procedure:

1. You will lie down on the examination table in the angiography room.
2. After the skin is disinfected and covered with a sterile cloth a local anesthetic will be given either in the groin or the inside of the elbow by means of an injection of about 10 ml lidocain 1 % (Xyloneural). Subsequently a puncture of an artery of the leg or arm is performed and a sheath will be put in place. Then a thin catheter is introduced via the sheath. The diameter of the catheter is about 1.2 to 1.8 mm (4-6F). The catheter is advanced into the main artery on the basis of an X-ray image and then guided into the intended

vessel; normally this takes only a few minutes. For placing stem cells e.g. in the pancreas the leg artery is commonly punctured.

- 3. Next a contrast material is injected via the catheter in order to show the individual blood vessels and to visualize the distribution. For a short time the contrast material causes a feeling of heat/warmth throughout the body, with the femoral access this is mainly in the lower part of the body and can sometimes involve a feeling like the start of a cramp in the calf. This feeling of heat/warmth lasts less than 10 seconds and is completely harmless. During the procedure you may be asked to briefly hold your breath.
- 4. Additionally it may sometimes be necessary – in order to assess the image of the vessels on the screen better – to administer a medication that temporarily blocks the movement of your intestines during the procedure. This medicine briefly causes a dry, bitter taste in the mouth and possibly also dizziness for a short time. This medicine must not be administered to a patient with increased intraocular pressure (glaucoma/ cataract). So please let us know if you suffer from glaucoma.
- 5. After confirming by angiography that the catheter has reached the target area the stem cells will be injected. After the application the catheter and sheath will be removed.
- 6. After the removal of the devices from the groin a special closure tool (AngioSeal®) will be put in place. This allows you to stand up immediately and move, albeit very carefully. Following another four hours rest you can be discharged. After the removal of the devices from the arm the site of the injection must be compressed manually until the bleeding has stopped (normally after 10 minutes), after which a pressure bandage is applied; otherwise due to the puncture of an artery and to the pressure of the blood, the puncture would not close. Therefore the pressure bandage has to stay in place for 4 – 6 hours and you will need strict bed rest during that time so no bleeding occurs or a hematoma (accumulation of blood in the tissue) is formed in the area of the injection.
- 7. A written report (protocol) is prepared of the procedure.
- 8. After the period of rest and bedside monitoring at the clinic, and provided that there were no complications, you can be transported by car or taxi to your home or hotel.

Possible side effects and complications:

- 1. Allergies for iodine containing contrast medium are rare and in most cases can be treated with medicines immediately. However, in very rare cases major allergic reactions may occur with an acute reduction of the blood pressure and respiratory and cardiac arrest.

As a rule this concerns patients who experienced severe allergic reactions previously. If you suffer from allergies you must inform us. For details see below.

- 2. Sometimes circulatory hypersensitivity reactions occur. These can usually be relieved quickly by using medicines to increase the blood pressure.
- 3. At the site of the injection bruising or vessel wall injury can occur. Major bleeding can result in considerable blood loss; it may then be necessary to operate immediately to remove the hematoma and to suture the blood vessel at the site of the injection.
- 4. Iodine contrast medium may rarely lead to a deterioration of renal function, or even to a renal failure. Therefore we might give you a special medication - saline in combination with ACC (Acetylcysteine) - to protect your renal function if your renal-parameters are slightly elevated (Creatinine and BUN). If there is already a severe renal insufficiency we most likely will not be able to perform an angiography. In most cases these complications can usually be treated successfully.

