

Patient:

CRM-number:

Date of birth:

Treating physician:

1. General information

Dear patient,

It is important that prior to the treatment you are well informed. Therefore please take your time reading the information below. If something is not clear, **if you would like more details about the procedure**, about the mentioned complications, about specifics for your individual case or about (very) rare risks, 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 (though not too big).

Exception: Patients with allergies.

You can and should take your regular medications – if needed bring the necessary medicines for your stay.

Exception: Blood thinners or anti-coagulation medicines.

For the observation time following the procedure you can bring something to read. To pass the time there will be a television in your room. We have our own cafeteria for family members accompanying you.

Afterwards you will not be able to drive home; therefore bring someone to take you home or travel by taxi.

2. More information about the IV treatment

Based on your previous examinations/medical evaluation it is necessary to perform the stem cell transplant via intravenous infusion in order to place the stem cells in the blood circulation. Mannitol (an old medication used as a diuretic for the brain and as a diagnostic to measure the kidney function) is used to open temporarily the blood brain barrier, so the cells and substances produced by the cells, so called neurotropic factors, can enter the brain.

The vein is punctured using a vein catheter, which will be removed after the treatment. Normally the procedure is not painful.

3. Course of the IV Treatment:

1. You will lie down on the examination table in the IV Treatment room.

2. After the skin is disinfected and covered with a sterile cloth. The doctor will make a puncture in a vein of the right or left arm. By means of a vein catheter, 10 ml/kg bodyweight Mannitol (20%) will be injected over 20 minutes.

3. After the infusion time, the stem cells are diluted and drawn up into a syringe under sterile conditions. The transplantation via IV is performed in "slow motion" so mixing with the blood can be successful. This reduces the risk of possible side effects. Afterwards the vein catheter is removed and a sterile bandage is applied.

Information and written consent form IV (Mannitol)

- **4.** You will stay in bed and are wheeled to the recovery room. You will have to stay there in a horizontal position (turning to the other side is permitted) under clinical observation for about 2-3 hours.
- **5.** After the rest and observation time in the clinic, provided there are no complications, you can be transported by car or taxi to your home or hotel.
- **6.** Once at home or the hotel you must drink plenty of fluids.

4. Possible side effects/complications:

- **1.** Allergy to Mannitol. Let us know if there are known allergies (see below).
- **2.** Sometimes circulatory hypersensitivity reactions occur. These can usually be relieved quickly by using medicines to increase the blood pressure.
- **3.** The same is true for possible nausea and vomiting - the right medicines usually help quickly.
- **4.** Occasionally complaints about urination can temporarily occur, especially in patients with underlying or added diseases like MS or prostate enlargement. For that reason too it is important to drink plenty of fluids after the IV treatment. In rare cases a one-time catheterization may be needed. For that reason, you will not be discharged until you have urinated spontaneously at least once.
- **5.** At the site of the injection bruising or vessel wall injury can occur. What may occur after IV treatment is a thrombophlebitis, extravasation, hematoma or an infection.

— **Please answer the following questions in order to reduce the risks of intervention and possible complications as much as possible (please underline/indicate clearly)**

	Yes	No
— Are you hypersensitive to medicines, bandages, chemicals, foods, antibiotics or anesthetics?	<input type="checkbox"/>	<input type="checkbox"/>
— Which? <input style="width: 600px;" type="text"/>		
— Do you have known blood-clotting problems?	<input type="checkbox"/>	<input type="checkbox"/>
— or do you use anti-coagulation medicines (i.e. Marcoumar, Sinthrome, Falithrom, Coumadin, Phenpro, Phengamma, ASS, Aspirin, Plavix, Aggrenox)?	<input type="checkbox"/>	<input type="checkbox"/>
— Which? <input style="width: 600px;" type="text"/>		
— Do you often have a headache?	<input type="checkbox"/>	<input type="checkbox"/>
— Do you have kidney or prostate disorder?	<input type="checkbox"/>	<input type="checkbox"/>
— A gastric ulcer or other gastro-intestinal disorders?	<input type="checkbox"/>	<input type="checkbox"/>
— Do you have diabetes / are you a diabetic?	<input type="checkbox"/>	<input type="checkbox"/>
— Have you undergone bypass surgery, do you have a stent implantation or pacemaker?	<input type="checkbox"/>	<input type="checkbox"/>
— Other important previous disorders: <input style="width: 600px;" type="text"/>		
— For women: Is a pregnancy possible?	<input type="checkbox"/>	<input type="checkbox"/>

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- By placing your signature below you agree with the proposed treatment (this also includes necessary measures in case of rare, but possible, complications). You also declare that you have been extensively informed about the IV (Mannitol) treatment by the treating physician, that you have been able to ask all your questions, and that they have been answered to your satisfaction.
- Remarks:

Zug, date:

Signature of the patient (or legal representative):

Signature of the physician: