

Information and written consent form

Lumbar Puncture



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 radio and television in your room.

We have our own cafeteria for family members accompanying you. Drinks will be provided for you.

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

When in the vehicle, make sure you can recline as much as possible.

The next 3 – 5 days you have to rest and should not exert yourself – maybe even report to work sick, at your request we will issue a statement.

2. More information about the lumbar puncture (LP)

Based on your previous examinations/medical evaluation it is necessary to perform the stem cell transplant via a lumbar puncture (LP) in order to place the stem cells in the spinal fluid space.

A lumbar puncture is a puncture of the spinal canal using a fine needle, beveled at the front, in the lumbar region (lowest vertebrae of the back) of the spinal column for extracting spinal fluid (nerve or cerebral fluid). Lumbar punctures are primarily performed to diagnose for instance inflammatory disorders of the nervous system such as meningitis or multiple sclerosis. The extracted fluid, which is usually clear like water, in such cases is then examined in various ways in the laboratory.

During the LP for the stem cell therapy a volume of spinal fluid is extracted that is equivalent to the volume of your own stem cells intended for transplantation, so as little pressure difference as possible occurs in your spinal fluid space.

Changes in the pressure of the spinal fluid can cause headache. This pain is not dangerous and rarely lasts longer than 1 – 2 days, but the pain can be uncomfortable especially when getting up from a horizontal position due to the changing pressure ratios.

In order to prevent complaints due to the loss of spinal fluid as much as possible you are advised to lie down - if possible – for 24 hours and to drink plenty of fluids.

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Course of the lumbar puncture:

— 1. Position

The lumbar puncture is performed while you are lying on your side with your legs pulled up (knees towards the chin, fetal position). This causes the lower part of the spinal column that is normally bent forward to now be bent backwards, which will make it easier for the needle to pass between the vertebrae and reach the spinal canal.

Particularly in (elderly) patients with severe degenerative symptoms of the spinal column or severe scoliosis (sideways curvature of the spine), as well as with excessive curvature of the spine forwards, it can be difficult to get access between the bone structures.

As an alternative the puncture can also be performed in a sitting position with a forwards bent upper body. If needed, on the basis of the individual condition of the spinal column or due to other conditions, this alternative can be chosen at the time of the procedure.

Generally, the benefit of lying on one's side is that it is more comfortable and that it further minimizes the risk of (very rare) complications. See 5 below.

— 2. After the skin is disinfected and covered with a sterile cloth a local anesthesia is administered at the site of the puncture, usually between the 4th and the 5th lumbar vertebrae at the level of the pelvic brim, by injection of approximately 5 ml lidocain 1 % (Xyloneural).

The lowest lumbar segments of the spinal canal do not contain spinal cord, only nerves ("roots"), i.e. nerve bundles that take care of the part of the body below that point. The spinal cord normally ends at about the level of the 1st lumbar vertebra.

— 3. Puncture of the lumbar spinal canal occurs under sterile conditions (face mask, sterile gloves) with a special needle with an outer diameter of approx. 0.9 mm, a hollow needle with an inner removable needle, (stylet) which is withdrawn to let the spinal fluid drip out and to administer the stem cells.

The physician can feel the resistance of the various tissues that have to be punctured, in particular the resistance of the dura, the hard membrane around the (brain or) spinal cord and knows then that the spinal canal has been reached.

In a few cases, with an exceptionally elastic dura and a narrow spinal canal, a type of electric shock in one leg or both legs can occur due to pressure on the nerve root lying beneath.

— 4. The inner needle (stylet) is removed and the spinal fluid that flows out is collected in a measuring tube so the exact amount of the transplant volume can be collected. A small amount (depending on the number of stem cell concentration vials approx. 1 – 2 ml) extra is collected in a syringe; this fluid is then mixed with the stem cells and reintroduced.

— 5. The stem cells, with a small additional amount of spinal fluid, are drawn up into a syringe under sterile conditions.

— 6. The transplantation via the placed LP cannula (tube) is performed in "slow motion" so the mixing with the spinal fluid and the distribution can be successful. This reduces the risk of possible side effects: back pain radiating to the buttocks and the legs or uncomfortable sensations in the legs.

Afterwards the lumbar cannula is removed and a sterile bandage is applied.

— 7. The patient is then transferred to a bed directly from the treatment table, wheeled to the recovery room and stays there in a horizontal position (turning to the other side is permitted) under clinical observation for 3 - 4 hours.

— 8. 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.

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	Yes	No
— Did you have complaints/problems during/afterwards?		
— Which? <input type="text"/>		
— Do you often have a headache?		
— Have you ever had a head injury or head surgery?		
— Have you ever had spinal column surgery?		
— Which? <input type="text"/>		
— Do you have a spinal column malformation (lumbo-sacral abnormalities)?		
— Do you have kidney or prostate disorder?		
— Which? <input type="text"/>		
— A gastric ulcer or other gastro-intestinal disorders?		
— Do you have diabetes / are you a diabetic?		
— Other important previous disorders: <input type="text"/>		
— For women: Is a pregnancy possible?		

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 procedure 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: