

Marrow Donor Program Belgium – Registry
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DONATION OF STEM CELLS FROM BLOOD, BONE MARROW OR LYMPHOCYTES BY A VOLUNTARY UNRELATED DONOR INFORMATION LETTER INTENDED FOR THE DONOR

Why become a hematopoietic stem cell (HSC) donor?

Every year, thousands of people with a blood disease that destroys their bone marrow or which means that it no longer functions are treated with a stem cell transplant.

These patients are treated with high doses of chemotherapy or with a combination of chemotherapy and radiotherapy. Unfortunately, this treatment destroys not only the abnormal cells, but also the precursor cells for blood production (known as stem cells). It is vitally important for these patients, following this kind of treatment, to receive a transplant of stem cells, which are collected from a healthy HLA-compatible voluntary donor. This is known as an allogeneic stem cell transplant. These stem cells can be collected either from bone marrow or from blood.

Donating HSC is a commitment. First and foremost, it is a personal, thoughtful decision which entails a genuine commitment since this donation can save a life.

- You will have a medical interview where you will be asked about your current and previous state of health, your personal life and contraindications.
This information is strictly confidential. It is essential that you reply truthfully during this interview to ensure your own safety and that of the patient who may have a transplant of your stem cells.
- You will give a blood sample on which tissue typing (HLA typing) is carried out. Using your tissue typing, it will be assessed whether you are compatible with a patient. The HLA typing and blood tests are carried out at the expense of the donor center.
- You must remain available to ensure that the collection runs smoothly.
- You must inform the donor center where you are registered about any change concerning your state of health or your contact details.
- The donation is voluntary, anonymous and unpaid.
- You sign a consent form to confirm your registration.
- You can revoke your commitment at any time, without having to give reasons.

Who can donate HSC?

Anyone who is in good health, between 18 and 40 years of age, and meets the criteria for blood donation can register as a stem cell donor. You can be asked to donate your stem cells up to 60 years of age, but after that you will automatically be removed from the national registry.

You cannot be a donor during pregnancy or while breast-feeding. Please do not hesitate to ask the doctor for advice.

Why donate stem cells from blood instead of from bone marrow?

The use of stem cells from blood instead of stem cells from bone marrow offers various benefits for the patient; for example, faster resumption of blood production and speedier recovery of the body's defence mechanisms that have been weakened after transplantation. This will increase the effectiveness of the transplanted cells against the disease.

There is a risk that the transplantation of stem cells from blood increases the risk of rejection from the donor to the recipient (known as graft versus host disease). This graft versus host disease, if it is not too pronounced, nevertheless has a beneficial effect of reducing the risk of recurrence of the disease.

For you, the donor, there is no need for general anaesthetic for donation of stem cells from blood and the risks inherent in donation are minimal.

The patient's attending physician may give preference to a certain type of stem cells, from blood or bone marrow, but the choice is entirely up to you.

Before a donation of stem cells from blood, bone marrow or lymphocytes

Before treating you with a view to stem cell collection, you will have a consultation with the doctor responsible for the collection. The doctor will ask you questions about your current state of health and illnesses that you may have had previously (for example, asthma, high blood pressure, diabetes, epilepsy, heart disease, hepatitis and jaundice, tropical diseases or time spent in countries where malaria or zika are present), possible surgical operations in the past, any allergies, medication that you take regularly, family antecedents of thrombosis or a tendency to bleeding and high-risk behaviour for transmission of infectious diseases (drug addiction, new/multiple sexual partners, etc.). A clinical examination will take place (possibly with a lung x-ray and/or an electrocardiogram) and a blood sample (for HIV serology and other tests such as for hepatitis B, C and syphilis) will be taken.

What happens during a donation of stem cells from blood?

To collect stem cells from the blood, a growth factor is used: G-CSF (Granulocyte Colony Stimulating Factor), which is a substance comparable to a hormone. G-CSF increases the production of certain white blood cells in bone marrow and blood, and mainly ensures that precursor cells known as stem cells are released in the blood.

You, as the donor of stem cells from blood, will have a daily subcutaneous injection of G-CSF for 4 to 5 days before the stem cell donation. G-CSF are generally well tolerated, but you may experience headaches, nausea, or aching bones or muscles (80% of donors), as well as a slight burning sensation at the time of the injection. These side-effects can easily be overcome with simple painkillers. Very rarely, allergic reactions may occur such as fever, chills or a rash.

The stem cells will be collected with the help of a special blood cell collection equipment, known as a cell separator. For this purpose, two peripheral venous catheters will be placed in both your forearms, if possible at the elbow. The blood will flow out of your body through one of the tubes to the machine, and return to the body via the other tube. On rare occasions, it is necessary to place a central catheter if your veins are not thick enough to allow stem cell collection by this method. In that case, a needle will be inserted into a wide vein in the neck or elsewhere, under local anaesthetic. In extremely rare cases, the donor may experience complications on placing of a central catheter, including bleeding and infections at the injection site and collapsed lung. In order to collect the stem cells, your blood will be pumped through the cell separator, so that the blood-forming precursor cells can be removed. The other components of your blood will immediately be returned. Apart from the vein puncture described above, the procedure is painless. No loss of blood is involved. During donation, the donor may feel light-headed or suffer chills, numbness or tingling around the mouth and cramp in the hands. These symptoms disappear after the completion of the donation.

The procedure, known as leukapheresis, lasts an average of four hours and is usually carried out in a single day. Sometimes, if it is impossible to collect enough stem cells in a single collection, you will be given an additional injection of G-CSF, and another leukapheresis will be carried out the next day. In very rare cases, it may be necessary to carry out more additional leukaphereses.

In most cases, you will be able to resume your normal routine after 1 to 7 days. It may take 1 to 2 weeks before you feel fully recovered.

In any case, you will be examined again by the doctor in charge of the collection 1 week, 1 month and 5 years after the donation. If you observe any side-effects or any change in your state of health in the meantime, please inform the doctor in charge immediately. If necessary, medical monitoring with specialist doctors will take place.

What happens during a donation of stem cells from bone marrow?

For the collection of bone marrow, a hospitalisation lasting 36 to 48 hours is required. The collection takes place under general anaesthesia in the bones of the pelvis. The principal risk of a bone marrow donation is that of the general anaesthesia. A doctor who is part of the collection team will collect a variable quantity of a mixture of blood and bone marrow, usually 1 to 1.5 litres. The operation lasts about 1 to 2 hours. If everything goes normally, you can leave hospital the day after the operation. Physically, after the bone marrow collection you may experience sore throat (32% of donors), muscle aches (24% of donors), insomnia (15%), headache (14%), dizziness (10%), loss of appetite (10%) and nausea (9%) due to the anaesthetic. You may also feel pain and experience bruising at the puncture sites, feel pain in the back and pelvis (84% of donors), as well as feeling tired (61% of donors). These symptoms will disappear after a few days.

It is recommended to rest for 1 week after the bone marrow donation. In most cases, you can resume your routine after 1 to 7 days. It may take a few weeks before you feel fully recovered. The average time for complete recovery after a bone marrow donation is 20 days (within 2 days for 5% of donors, within 7 days for 18% of donors, within 30 days for 71%, within 6 months for 97% and within 1 year for 99% of donors).

In very rare cases, a local infection may occur, which requires appropriate treatment. There is a very limited risk of phlebitis (vein inflammation), which justifies preventive use of heparin during and possibly after anaesthesia. Under certain circumstances, you can be given a blood transfusion to compensate slight anaemia as a consequence of the donation.

In view of autologous transfusion, blood collections must occur (usually 1 to 3 pouches) during the month before the bone marrow collection. This blood will be administered to you at the end of the bone marrow collection to compensate the volume of the bone marrow collected. The preparation and storage of the blood is carried out by the blood transfusion center.

In any case, you will be examined again by the doctor in charge of the collection 1 week, 1 month and 5 years after the donation. If you observe any side-effects or any change in your state of health in the meantime, please inform the doctor in charge immediately. If necessary, medical monitoring with specialist doctors will take place.

What happens during a donation of lymphocytes?

You have already donated stem cells from bone marrow or blood for a patient who was treated with a transplant of hematopoietic (blood-forming) stem cells.

Unfortunately, that transplant was not a complete success. The reasons for failure may be due to rejection of the graft, or a result of a recurrence of the illness. These complications can be fatal for the patient in the short term. The ideal treatment for these complications consists of administering lymphocytes originating from the same donor as used for the transplant.

Lymphocytes belong to one of the most important groups of white blood cells. If the patient suffers a relapse, these lymphocytes can recognise the tumour cells, attack and destroy them. If the graft is rejected, then they can attack the patient's immune system and prevent the graft being rejected. These lymphocytes absolutely must originate from the same initial bone marrow or peripheral stem cell donor.

No medication is needed for the donor in preparation of lymphocyte collection. Lymphocytes are collected via leukapheresis, just like stem cells from the blood. A donation of lymphocytes can be completed in 4 hours.

In some cases, only very few lymphocytes are needed, and it will suffice to collect a pouch (about 450 ml) of blood via a peripheral blood vessel without leukapheresis.

Other useful info about donation of stem cells from blood or bone marrow or of lymphocytes

For the day of the medical examination and the period of incapacity for work due to side-effects of the donation, the doctor in charge of the collection can issue you with a medical certificate, provided that your employer agrees. The donation usually results in 1 to 7 days of incapacity for work. You will not receive any financial remuneration from the registry or the transplant center for your period of incapacity for work.

For each donor, insurance is taken out to cover the eventuality of complications occurring that are not among the expected side-effects of the donation or for any bodily harm that is a consequence of the donation. You will find more information about this in the enclosure with this information letter (Information letter about donor expenses and anonymous communication).

You can consult the results of your blood tests if you wish. In the event of abnormal results, you will be informed about this as soon as possible by the doctor. These results will be passed on via the MDPB-R to the patient's transplant center.

The donation is anonymous, free of charge and voluntary, and cannot be associated with any financial or other remuneration. In the enclosure sent with this information letter (Information letter about donor expenses and anonymous communication), you can find more information about which expenses that you have incurred may be refunded.

If you opted for a donation of stem cells from blood, in exceptional cases (< 1%) it may happen that the mobilisation fails. In that case, you may be asked to donate bone marrow. You are free to choose whether you consent to this or not, without any obligation.

You also have the option to refuse this type of donation in advance, when completing your consent form.

It is also possible that in the months following your donation, you will be asked again to donate lymphocytes from blood for the same patient (this time, no injections of growth factors are required) or in rare cases, to donate stem cells again, either from bone marrow or from blood. The decision whether to go ahead with an additional donation is up to you, without any obligation.

If the quantity of HSC collected exceeds the quantity to be administered, the surplus may be frozen and stored for up to 5 years at the transplant center. These cells may only be used for the patient for whom they were donated. If the patient should die, the cells must be destroyed. Before they are destroyed, the patient or his/her doctor will be contacted.

You can decide for yourself whether you consent to the cells that can be destroyed nevertheless being stored for scientific research. Any scientific research shall be submitted in each case to the Medical Ethics Committee for approval.

If, due to sudden and unforeseen circumstances, the patient's clinical condition does not allow a transplant at the time that was agreed, your HSC will be frozen, provided your consent, and stored by the patient's hospital for later use. This procedure is exceptional.

News about the patient for who you donated can only be given to you in anonymised form, after the consent of the Belgian Registry (MDPB-R), the patient and the transplant center. This data will always remain anonymous.

The law prescribes that the donor may change his/her mind at any time and withdraw consent 'at any time'. Nevertheless, it is clear that, after the beginning of the preparatory treatment (conditioning), which will destroy the recipient's bone marrow, withdrawal by the donor may be fatal for the recipient.

The data concerning your donation may be the subject of analysis, in which anonymity and confidentiality will be strictly maintained as prescribed by the legislation on protection of privacy.

If you are registered as a donor at a particular donor center, that does not necessarily mean that the collection has to take place at the collection department of the same institution.

Stem cells will be used in the future for other applications than stem cell transplants, e.g. in regenerative medicine. In that case, a separate consent form will be required.