

REGISTRATION OF PROSPECTIVE STEM CELL DONOR INFORMATION LETTER FOR THE DONOR

Why become a donor of haematopoietic or blood-forming stem cells (HSC)?

Every year, new prospective donors are required in order to ensure the likelihood of a match. After all, every year there are prospective donors who are no longer eligible through death, illness, old age etc. You can help by becoming a stem cell donor.

- You donate **anonymously** with respect to the recipient: you do not know who receives your stem cells and equally, the recipient does not know who the stem cells come from. The recipient may be a Belgian or international patient. Your personal data, however, are kept for various reasons and remain linked to your donor material.
- You are **well-informed**: you receive all the relevant information about the donation, the process and potential risks. You can make a considered decision on these grounds. The law states that you may change your mind and withdraw at any time.
- You donate for **free**: you do not receive any compensation, financial or otherwise. You are however insured to cover any physical injury which may occur as a result of your donation.

What are stem cells?

A stem cell is a cell that is capable of changing into another type of cell. Stem cells are responsible for the creation and development of living organisms. They also ensure that certain cells in our body with a short lifespan are 'refreshed'. This concerns blood stem cells or haematopoietic stem cells. They are responsible for creating red blood cells, white blood cells and blood platelets. Haematopoietic stem cells are found in bone marrow, blood and umbilical cord blood.

When is stem cell therapy necessary?

Bone marrow can become sick in children as well as adults. This occurs in the case of leukaemia and other conditions. Other patients may have a congenital defect of the bone marrow stem cells, which leads to insufficient healthy blood cells being created.

Stem cell therapy is also often used to counter the destructive effects of chemotherapy on the blood cells.

Inserting the undifferentiated stem cells - cells that do not yet have a clear end purpose - of healthy donors into the bloodstream of sick patients increases the likelihood that they will once again be able to produce healthy blood themselves.

How does stem cell therapy work?

Stem cell therapy involves searching for new stem cells that can replace defective or missing stem cells in the patient's body.

1. Searching for healthy stem cells

When searching for healthy cells, we first check whether stem cells from the patient's own blood can be used. This depends on a number of factors but primarily the process of the patient's illness. If their own stem cells are no longer usable, we must look for a suitable donor. Patients can only be treated with stem cells originating from a donor with the same tissue type. This is the challenge: there are tens of thousands of possible tissue type combinations.

1. We first look at the immediate family. The best chance of finding the same tissue type is in siblings (1 in 4) as half of the tissue type comes from the father and the other half from the mother.
2. The donor database is only involved if there is no family or no match in the immediate family. We search among all Belgians who have registered as stem cell donors.
3. No Belgian match? Then there are stem cell donors all over the world who are willing to help.

2. Collecting healthy stem cells

We can collect healthy stem cells from the bone marrow or blood of adults or from the umbilical cord blood of newborn babies.

From bone marrow

Bone marrow contains billions of stem cells that grow into blood cells throughout our lives. Bone marrow is found in the hollow and flat bones of our bodies, such as the pelvis and sternum. We can extract healthy stem cells by puncturing the bone under general anaesthetic.

From blood

Blood does not usually contain very many stem cells but by administering specific medication to a donor - bone marrow growth factor - we can encourage stem cells from the bone marrow to move into the blood. This ensures that at a certain moment the blood will contain a lot of stem cells which we can then collect through blood collection. Extracting stem cells from blood is therefore straightforward and can be done without anaesthetic. This method also has benefits for the patients receiving stem cells from blood. For example, blood production resumes more quickly and the body's defence mechanisms also recover more quickly. The quantity of stem cells in the donor will be restored to their initial level within 10 days, whether extracted from bone marrow or blood.

From umbilical cord blood

Following birth, the umbilical cord and placenta still contain quite a lot of the newborn's blood. This 'umbilical cord blood' is relatively rich in stem cells. By collecting the umbilical cord blood soon after birth and enriching the stem cells in the laboratory, we can freeze these stem cells which can then be stored for later use by a patient needing a stem cell transplant.

3. Administering healthy stem cells

Stem cells are administered by transfusion. The new stem cells make their own way from the blood to the bone marrow, where they get to work making new blood.

If the tissue types of the donor and patient are a perfect match and the transplant is successful, the donor stem cells will grow in the patient's bone marrow cavities. There they can start creating healthy blood once again.

How can you register as a candidate?

1. Take the donor test at www.stamceldonor.be. This checks whether you are a suitable donor. You are eligible to register for stem cell donation until the age of 40. You can be asked to donate stem cells until the age of 60, when you are automatically removed from the national registry of available donors.
2. Complete the online registration form at www.stamceldonor.be.

What's next?

Based on your online registration, you will be invited for a medical examination and sample collection. What can you expect?

Medical check

You go through a medical questionnaire together with the doctor, who will ask a number of questions regarding certain diseases (e.g. asthma, high blood pressure, diabetes, epilepsy, heart disease, hepatitis and jaundice, tropical diseases and visits to countries where malaria is prevalent). Any past surgical procedures will be discussed, as well as allergies, medication, family history of thrombosis or bleeding tendencies, addiction or behaviour with a heightened risk of sexually transmitted infections (STIs).

Sample collection

Your blood is tested to determine your tissue type. This information is stored in the Belgian bone marrow donor registry.

Which documents do you need to sign?

You must give informed consent for the sample collection by signing a 'declaration of willingness'. This entails that you are entitled to all the relevant information about the donation, how it will be carried out, the associated risks and so on. You can change your mind and withdraw at any time.

What do you need to bring?

Your ID card.

1. Your details will be stored in the Belgian Bone Marrow Registry.

The Bone Marrow Registry works with donor centres and hospitals. A prospective donor can register there and give a blood sample.

- The registry manages the database and all the data on prospective donors and their tissue types.
- When a patient request arrives, the registry goes in search of donors with identical tissue types. We do this by consulting Belgian and international donor banks and umbilical cord blood banks.
- Once a compatible donor has been identified, we coordinate the administrative follow-up, until the eventual transplant is carried out.

2. Next, you wait until you are potentially called upon to become a donor.

In the case of a match between your stem cells and those of a patient, we will contact you immediately. We check whether you are still willing to donate and guide you through the donation process. We will also continue to follow up with you afterwards.

1. Your consent

We contact you to determine whether you still wish to donate.

2. Extra checks

We take another blood test to check if everything is in order. If it is, we will make an appointment for stem cell donation and start the preparation.

3. Preparing for stem cell donation

We will carry out a comprehensive medical examination at least three weeks before collecting your stem cells.

Over the five days prior to collection, you will receive subcutaneous injections of growth factors. These enable stem cells to be 'harvested' from your blood. Most donors handle the injections well. Flu-like symptoms may occur on occasion, or bone pain in the pelvis or sternum. You can take a painkiller for this.

4. Donation

The donation takes place in a hospital. We take blood from an artery, extract the stem cells and return your blood to your body through another artery. It does not hurt. The whole process takes around four hours.

5. Transplantation

Your stem cells are then administered to the patient, whose life may be saved by your stem cells.

6. Ongoing monitoring

We will carry out medical checks to ensure that you are completely physically in order after a week, a month, a year and five years.

Scientific research

We also use the data we collect during your tissue typing for scientific research in relation to transfusion, for epidemiological purposes or with the aim of gaining greater insight into medical conditions and their treatment, for internal validation and to optimise reporting on operational processes related to our public service and public

health duties as a bone marrow registry or cooperative centre.

Based on the data we collect during tissue typing, we may invite you for scientific research or innovative medical purposes such as regenerative medicine and immunotherapy. Naturally, we will also request your explicit permission in such cases.

What do we do with your personal data and how do we protect it?

- Who is responsible for processing your personal data?

The Marrow Donor Program Belgium – Registry, Motstraat 42, 2800 Mechelen, a subsidiary of the Belgian Red Cross, a public utility institution with legal status under the Act of March 30th, 1891, is the controller of your personal data, together with the cooperative centres with regard to the data the cooperative centre in question collects from you.

Cooperative centres are:

- The donor centre where the initial sample is taken;
- The hospital/collection centre where stem cells can be collected if a match is found; and
- The stem cell bank receiving the stem cells from hospitals.

The bone marrow registry and the cooperative centres have entered into an agreement to this effect. If you would like more information on the essential content of this agreement, please contact the DPO of your cooperative centre or the DPO of the bone marrow registry (see below).

- Which of your personal data do we process?

As a (prospective) stem cell donor, we process the following of your data:

- Standard personal data such as name, address, national registration number, telephone number etc.
- Sensitive personal data such as genetic data (DNA), ethnicity, health data (incl. blood group, infectious diseases, HLA results etc.).

- What are the purposes of and legal grounds for the processing of your personal data?

We process your personal data for various purposes:

- To assist persons in finding suitable human tissue in order to be able to perform the transplant that is vital to these persons, to provide healthcare and/or for reasons of public interest in terms of public health.
- To provide sufficient safe stem cells, including informing and contacting people about the donation of stem cells. This is required in order to provide healthcare and/or for reasons of public interest in terms of public health;
- We also process this data for the purposes of scientific research in relation to transfusion, for epidemiological purposes or with the aim of gaining greater insight into medical conditions and their treatment, for internal validation and to optimise reporting on operational processes related to our task as a bone marrow registry or cooperative centre in the service of public interest and public health;
- To invite you to become a blood, plasma or platelets donor. This takes place on the grounds of public interest in terms of public health;
- To call on you to donate blood and/or plasma if necessary for the treatment of a specific patient. This takes place on the grounds of public interest in terms of public health; and

- Finally, we process your personal data for the purposes of the management of complaints and disputes. This takes place on the grounds of our legitimate interest in being able to deal with a complaint or dispute and to indemnify our rights and interests.

- Who receives your personal data?

We share your data with:

- Processors who provide support services such as the World Marrow Donor Association, an external data platform and portal, call centres, text and email services, software suppliers etc.
- Domestic and foreign bone marrow registries and cooperative centres (in encrypted form) in order to be able to connect patients with suitable stem cell donors or to allow them to carry out scientific research in the context of transfusion, for epidemiological purposes or for the purpose of better understanding medical conditions and their treatment;
- Hospitals/doctors that may be able to facilitate stem cell donation;
- Hospitals/doctors that may be able to facilitate stem cell transplantation (in encrypted form);
- Insurance companies in order to provide cover in the case of complications that are not among the expected side effects of donation or for any physical harm arising from the donation;
- Blood organisations if you would like to become a blood, plasma or platelets donor;
- The Federal Agency for Medicines and Health Products in the scope of their blood monitoring authorisation; and
- Recognised laboratories with whom we work.

- Do we share your data with countries or organisations outside the European Economic Area?

We share your data with stem cell registries and cooperative centres outside the European Economic Area in encrypted form in order to be able to connect patients outside the European Economic Area with suitable stem cell donors. This also allows those stem cells registries and cooperative centres to carry out scientific research in the context of transfusion, for epidemiological purposes or for the purpose of better understanding medical conditions and their treatment.

We also use processors (external data platform and portal, software suppliers etc.) outside the European Economic Area. We provide suitable safeguards through standard clauses regarding data protection or other suitable safeguards. These are available from us for review.

- For how long do we keep your data?

Your data will be stored in accordance with the legal requirements, namely for a period of at least 30 years and no longer than 50 years.

- What are your rights as a data subject?

You have several rights:

- You have the right to **access** your personal data. In this way you can check which of your personal data we process.
- You have the right to the **rectification** of your personal data. In this way you can have incorrect personal data about you corrected.
- You have the right to the **erasure** of your personal data. This right allows you to have us 'forget' you and delete any details we have about you. We are not always obliged to erase your data at your request. This is only required in the cases determined by law.
- You have the right to **restrict** processing concerning you. In this way, you can ask us to limit the processing we carry out. We will then continue to store your data but its use will be made stricter. We are not always obliged to grant such requests. This is only required in the cases determined by law.
- You have the right to **object** to the processing. In this way you can refuse the further processing of your data by Belgian Red Cross-Flanders. We are not always obliged to grant such requests. This

right can only be exercised when we are processing your data on the grounds of legitimate interest or to fulfil a duty in the public interest.

- You have the right to withdraw your **permission** if the processing takes place on the basis of your permission.
- You have the right to **object** to the processing of your personal data for recruitment and communication purposes.
- You have the right to **data portability**. In this way you can quickly move, copy or pass on your data from one controller to another. This right complements the right to access. It offers you a way to easily control your own data and use it again. This right can only be exercised when the processing relies on your permission or on an agreement you have entered into with us.

- Who can you contact in the case of questions regarding the processing of your personal data?

The bone marrow registry and all cooperative centres have a Data Protection Officer (DPO). It is the specific duty of this person to monitor how the data may be used and how it must be protected when we process it.

In case of any requests or queries concerning the processing of your personal data, you can contact the DPO of your cooperative centre:

- By post: *(To be completed by each center)*
- By email:
- By telephone:

The DPO of the bone marrow registry can be contacted as follows:

- By post: Rode Kruis-Vlaanderen, t.a.v. DPO, Motstraat 40, 2800 Mechelen;
- By email: DPO@rodekruis.be
- By telephone: 015-44 33 86

- Do you wish to submit a complaint to the Data Protection Authority?

If you have a complaint, this must be submitted to the supervising authority. In Belgium, this is:

Gegevensbeschermingsautoriteit
Drukpersstraat 35
1000 Brussel
contact@apd-gba.be
tel. 0032 2 247 48 00