Sahlgrenska University Hospital
Section for Haematology and Coagulation

INFORMATION & CONSENT

Stem Cell Donation

Information & Consent Stem Cell Donation, Family Donor

This information is addressed to those who may become stem cell donors and it includes a description of the requirements for becoming a donor and how a donation is carried out.

Introduction

Background

The bone marrow contains haematopoietic (blood-producing) *stem cells*, which can create all types of blood cells. Transfer of these stem cells from a donor to a patient is called an *allogeneic stem cell transplantation*. This form of treatment is mainly used for malignant haematological diseases. The donor may be related to the patient, usually a sibling (sometimes a parent or a child) *or* be an unrelated donor from an international registry. It is only possible to perform an allogeneic stem cell transplantation if the *tissue type* of the donor matches that of the patient.

Test for tissue-typing

The tissue type can be determined with a blood test. The test is performed by us or where you live, e.g. at your health care centre, in this case we will send test tubes and a referral to you. After a few weeks, we will let you know if you have a matching tissue type.

Voluntariness

Donating stem cells is voluntary. In case of any doubt, you may choose to refrain without divulging the reason. If, on the other hand, you choose to donate but change your mind *after* the start of the patient's transplantation treatment, this may have serious consequences for the patient. If you have been asked, but hesitate to become a donor, we encourage you to contact us even before the taking of blood samples for tissue typing. Call the transplantation coordinator during office hours or send a message to the address below. You never have to give us any explanation as to why you do not want to become a donor.

If you have a matching tissue type

Medical examination and information

If your tissue type matches the patient's tissue type, you will be informed of this *before* the information is given to the patient. If you are positively inclined to donating stem cells, we will invite you for a visit where you will get information and a medical examination that includes testing for blood-borne infections (e.g. HIV, hepatitis, syphilis). You will also fill in a health declaration. The purpose of the visit is to make sure that the donation can be carried out in a way that is safe for both you and the patient, and to give you an opportunity to ask questions.

Any information about you that may appear at the medical examination is confidential, but you have the right to be informed of all results from the examination.

If a donation is being considered after the medical examination and information, we will inform the patient of the *relevant* results from your medical examination, such as viral response, blood type and a summary of your state of health, and of the fact that you are a suitable donor (but you can of course say more yourself, if you want to).

Registration and consent to donation
Before and after a *stem cell or bone marrow donation*, we register information concerning your donation in our registries for planning, follow-up, evaluation and improvement of the healthcare that we provide. Information concerning e.g. sex, age, tissue type and previous viral diseases will also be reported in encoded form to both Swedish and international registries, such as EBMT, a major European registry belonging to the European Society for Blood and Marrow Transplantation, and CIBMTR, the Center for International Blood and Marrow Transplant Research.

The purpose of the registration is to improve the quality of the treatment and to enable research and development.

For collection and storage of this information, we need your written consent. There is a form for this purpose at the end of this text. We also need your written and oral consent to collect stem cells from you as a donor.

Processing of your personal data according to GDPR
The Board of Sahlgrenska University Hospital is responsible for the processing of personal data. According to GDPR, you have the right to request information about what personal data is being processed. It is the Data Protection Officer who is responsible for ensuring that your personal data is processed in a legal, correct and secure way. If necessary, the Data Protection Officer can help you get information about what has been registered and make sure any corrections are made. The Data Protection Officer can be reached at the address: Sahlgrenska Universitetssjukhuset, Dataskyddsombudet, 413 45 Göteborg. Phone 031-343 27 15, sahlgrenska.universitetssjukhus.dso@vgregion.se.

Stem cell donation – How is it done?

The bone marrow contains haematopoietic stem cells. There are two ways to collect stem cells from a donor, either (1) via the blood (stem cell apheresis or *harvesting of peripheral stem cells*), or (2) directly from the bone marrow (*bone marrow harvesting*). As a donor, you have the right to choose which type of stem cell collection that you prefer.

1. Donation of peripheral stem cells
By using G-CSF medication, the stem cells inside the bone marrow can be attracted into the blood and from there they can be *harvested* (collected) by using centrifugation technology, *apheresis*. G-CSF is given as an injection under the skin for 4-5 days before a planned donation. Skeletal pain is a common discomfort during the days of treatment. This pain, which usually disappears within 48 hours after the donation, can be alleviated with painkillers containing paracetamol (e.g. Alvedon® or Panodil®). You should not use pain medication that contains acetylsalicylic acid during the treatment. Please contact us if anything is unclear concerning your medication or if you fall ill before or during the donation process.

The stem cells are being collected for 1-2 days. An apheresis takes 3-5 hours each time and requires that you have a thin plastic tube (peripheral venous catheter, PVC) in each elbow pit. In rare cases, you need to insert a central venous catheter (CVC), which is a thicker plastic tube, in a larger blood vessel in the throat or groin for sufficient blood flow. Your blood will be led into a so called apheresis machine, which uses centrifugation technology to collect stem cells, while the other parts of the blood (e.g. red blood cells) are returned to you.

During the collection procedure, you may experience discomfort in the form of a tingling in your fingers and around your mouth. These symptoms are harmless and can usually be eliminated by using lime.

Occasional very rare but serious side effects (blood clot and spleen damage) have been described during G-CSF treatment. We recommend that you avoid sitting still for long periods of time, e.g. flights, for the duration of the G-CSF treatment and the following week. Since the spleen is sometimes enlarged, you should not, during the same time period, engage in intense physical activities, such as ball games or other activities where there is a risk of violence to the abdomen.

If you experience abdominal pain, swelling or other symptoms that are unclear to you, you should contact the transplantation coordinator (office hours) or Ward 141 (other times).

You cannot normally work or do school work during the stem cell harvest, nor during the days immediately before and after the donation.

If you have to travel a long distance, we can arrange overnight accommodation in connection with the cell collection, but normally you go home after each day's collection.

2. Bone marrow donation

Collection of stem cells directly from the bone marrow, *bone marrow harvest*, requires that you are hospitalized for one or two days.

The blood loss during a bone marrow harvest is sometimes considerable and you may need to receive a blood transfusion in connection with the harvest. If possible, you can use your own blood for this transfusion by donating blood at your local blood establishment on two occasions, about 4 and 2 weeks before the donation. This blood will be stored to be used only for you. If further blood transfusion is required, blood from blood donors will be used.

The bone marrow harvest will take place in the operation ward, with anaesthesia. During anaesthesia, you are lying on your stomach on the operating table and two doctors are extracting bone marrow with syringes from the posterior part of your pelvis during approximately two hours.

There is a small risk of serious complications in connection with narcosis or anaesthesia. After the bone marrow harvest, most patients have a sore pelvis and may need painkillers. Normally you can go home the day after the harvest and you will be on sick leave for about a week.

Transplantation
The cells that you have donated are given to the patient on the same day within 48 hours. If more stem cells are collected than are required for the transplantation, we sometimes freeze the excess, which may be used for the patient, e.g. in case of a relapse. The cells may not be used for any other purpose and will be discarded when it is deemed that they are no longer needed.

Economy
As a donor, you can apply for compensation for e.g. loss of income and travel expenses. There are special information leaflets for this purpose. You can also get more information and help from our counsellor.

After the donation

One month after the donation, a routine check-up of your blood count will be carried out, preferably at your health care centre. The results will be sent to us and we will call and tell you the results and check with you that everything is fine.

Supplementary donation

If, in the future, the patient to whom you have donated stem cells should need more stem cells or other types of blood cells, particularly lymphocytes (a kind of white blood cells), you may be contacted by us again. It is entirely voluntary to donate another time. It is not a requirement, but we would appreciate it if even before the first donation you can tell us how you would view such a request.

If a lymphocyte donation is being considered, you will be called for a new visit for information and a medical examination. The process will be carried out here, in the same way as for the collection of peripheral stem cells, but unlike the stem cell donation, there is no need for G-CSF injections before the collection.

The lymphocytes are collected on one day during a few hours using an apheresis machine. The blood is conducted via venous catheters into the machine that is collecting lymphocytes, while the rest of the blood is sent back. Usually a peripheral venous catheter, PVC, is sufficient, and a central venous catheter, CVC, is only needed in rare cases. You may experience symptoms such as tingling. These symptoms are harmless and are eliminated by using lime.

Contact

Address
Transplantation Coordinator, Haematology Unit, Section for
Haematology and Coagulation
Bruna stråket 5 våning 5
413 46 Göteborg

Phone

Transplantation Coordinator	031-342 37 67
Apheresis Unit	031-342 73 70
Ward 141	031-342 11 41
Counsellor	031-342 99 38 or 031-342 74 55

Informed consent at stem cell donation

1. I have received written and oral information about stem cell donation.
2. I have received information about risks in connection with stem cell donation.
3. I have received information about and consent to testing, examinations and physical examinations as part of the health investigation.
4. I have been informed that I am entitled to receive results from tests and examinations.
5. I consent to stem cell donation.
6. I consent to the use of my stem cells for stem cell transplantation for the intended patient.
7. I consent to the freezing of cells in connection with the donation and to the use of these cells for the intended patient at a later time.
8. I have been informed that the cells will not be used for any other purpose and that they will be discarded when it is deemed that they are no longer needed.
9. I am aware that my commitment is voluntary and that I have the right to change my mind at any time. However, I am also aware that such a decision, after the patient's treatment has started, may have serious consequences for the patient.
10. I consent to give access to my previous medical records, if such exist, and to the use of information included in these records, as part of my health investigation.
11. I consent to the recording of all information concerning my stem cell donation in my medical record and in local, Swedish and international registries.
12. I consent to the sharing of information about my investigation and test results between the parties concerned with the donation and to the transfer of this information by fax.
13. I consent to the fact that this stem cell donation involves informing the receiving patient and the responsible transplantation doctor of all relevant results of my health investigation, such as viral response, blood type and a summary of my state of health.

I have read this information and consent to the above statements:

Date Signature

_____

Name in block letters

_____

Personal identity number

Oral information given by:

_____

This page should be given to the BMT Coordinator at the Sahlgrenska Haematology Section and be scanned into the medical record of the donor.