The ROYAL MARSDEN
NHS Foundation Trust

Donating stem cells for your own use

Haemato-oncology Unit

Patient Information

Contents

Introduction

This booklet has been written to help people who are over the age of 16 years to understand what is involved in the stem cell collection (harvesting) process and aims to guide you through each stage of the process if you consent to the procedure.

What are stem cells?

Stem cells are immature cells that are found in the bone marrow (the spongy material that fills the bones and produces new blood cells). Stem cells can grow and divide into mature red blood cells needed to carry oxygen, white blood cells needed to fight infection, or platelets to help blood clot. The type of blood cell a stem cell develops into is determined by the needs of your body, and through the action of substances called growth factors.

Why do you need to collect my stem cells?

One of the future treatment options available to you is high dose chemotherapy. If you have this treatment you will need to have a stem cell transplant.

High doses of chemotherapy will damage your bone marrow. The longer it takes for your bone marrow to recover the longer you will be prone to infections, anaemia and bleeding. We therefore collect and store your own stem cells for you, before your high dose treatment, so that they can be returned to you through a drip into one of your veins after you have had your high dose treatment. The stem cells will return to your bone marrow and start to produce the different blood cells you need to help your bone marrow to recover more quickly.

What happens first?

Your consultant haematologist has decided that you may benefit from high dose treatment and has therefore referred you to the stem cell transplant team at The Royal Marsden. Here we will assess you further and plan for this procedure.

If you have previously had disease in your bone marrow, you may need a bone marrow biopsy carried out to find out if we can proceed to a stem cell collection. The transplant team will check the result before you start the treatment to collect stem cells.

For certain diseases, re-staging scans are done to let us know how well your previous treatment has worked. The transplant team will check that your previous scans are reported, and will organise any new scans if necessary.

Your transplant consultant will ask a stem cell transplant nurse co-ordinator to organise the stem cell collection. The co-ordinator is an experienced nurse who will give you a full explanation of what the stem cell harvesting procedure involves. You will have the opportunity to ask questions and we will give you a contact number should you have any problems or questions at a later date.

We will ask you to attend the hospital three to four weeks before the pre-arranged stem cell donation date for a consultation and medical examination. The purpose of the examination is to confirm your fitness to undergo a peripheral blood stem cell collection and to assess your veins to identify if there is a need for central venous access. Consent for the procedure will be taken during this consultation.

It is a legal requirement for all patients having a stem cell collection to have routine blood tests for infection screening within the 30 days before the collection takes place. The infections tested for include Hepatitis B and C, Cytomegalovirus (CMV), Human Immunodeficiency Virus (HIV), Human T cell Lymphotropic Virus (HTLV) and Syphilis. The results are usually available within a few days.

These tests must be discussed with you before they are carried out and we will ask for your consent agreeing to have the HIV test. All results are confidential and we will send a copy to your GP only if the HIV test is positive and with your permission. If any of the results are positive and could have implications for your health or the donation, for example, the HIV test, we will call you back to the clinic to discuss the results.

It is not possible to collect stem cells if you are pregnant and therefore females who have reached puberty and are still of child bearing age will be asked to have a blood or urine pregnancy test as part of routine transplant preparation.

A report of this medical examination will be sent to your GP. During the medical examination, you will have the opportunity to discuss the donation process in more detail and ask any questions that you may have.

Please read the rest of this booklet to find out more about the donation procedure.

Will I donate stem cells from my bone marrow or bloodstream?

These days it is usual for patients to donate stem cells from the bloodstream as this tends to provide a greater number, however in some very rare circumstances we still use a bone marrow harvest. Your clinician will discuss this with you.

How is the peripheral blood stem cell collection carried out?

'Mobilising' stem cells from the bone marrow into the bloodstream for collection

To collect stem cells from the peripheral blood, the stem cells have to be encouraged to move from the bone marrow into the circulating bloodstream. This is known as 'mobilisation'. The exact method for collecting stem cells may differ from patient to patient dependent on individual factors such as disease type and their previous treatment.

Granulcyte colony stimulating factor (G-CSF) alone

It is possible to mobilise stem cells by using only G-CSF. G-CSF occurs naturally in the body and is one of a number of human growth factors that encourage and regulate the production of new blood cells in the body. A short course of additional G-CSF as a drug encourages the stem cells to rapidly divide in the bone marrow and mobilise into the peripheral blood in sufficient quantity to be collected. G-CSF can be manufactured synthetically in a form identical to the natural human variety and has been licensed for use for this purpose.

What are the risks and side effects of G-CSF?

The most frequent short-term side effect associated with G-CSF is bone and muscle pain, which can range from mild to quite painful, including pain in the chest and can usually be controlled with ordinary painkillers such as paracetamol. Less common side effects of G-CSF include insomnia, headache, fatigue, nausea, vomiting and flu-like symptoms including night sweats. There have been some rare reports (less than one in 1000 patients) of allergic reactions. These reactions include temporary changes in the way the liver works and skin rashes. This occurs in a very small number of patients and usually after prolonged treatment with G-CSF.

There is a theoretical risk that the use of G-CSF might contribute to the development of medical problems. In practice there is no evidence of any long-term medical problems in the thousands of donors who have received this drug. Nevertheless, studies are being undertaken which are designed to detect any possible long term side effects in people who have received G-CSF. There is also collaboration with other blood stem cell collection centres in Europe, North America, Japan and Australasia to see if they have encountered any problems. None of these centres has identified any unexpected side effects due to G-CSF.

We believe that the risk of giving G-CSF to patients is exceedingly low. However, we have a responsibility to ensure that the procedure of collecting blood stem cells from patients is as safe as it possibly can be, both in the short and long term. If any significant new data emerges, we will inform past and future patients.

Please note: aspirin and anti-inflammatory medication such as ibuprofen can affect the clotting ability of blood. They must not be used for pain relief during the donation process.

How is the G-CSF given?

G-CSF is given as an injection just under the skin, at about the same time each day.

The injections can be given by a:

- a district nurse
- a nurse at the hospital
- a family member
- yourself.

If you or your family want to administer the injections a nurse will teach you how to do it.

Chemotherapy and G-CSF

We sometimes use a combination of chemotherapy followed by daily G-CSF injections. As your white blood count recovers following the combination of ‘treatment’ chemotherapy and G-CSF your stem cells will move (mobilise), from your bone marrow to your peripheral blood. These stem cells can then be harvested.

The chemotherapy infusion and hydration takes approximately four hours in the daycare setting, however you may be there for most of the day for blood test results.

You will be given a protocol informing you of when to take the G-CSF injections and the dose.

As your blood white cell count recovers following the combination of cyclophosphamide and G-CSF your stem cells should move (mobilise), from your bone marrow to your peripheral blood. These stem cells can then be harvested.

What are the risks and side effects of chemotherapy?

The side effects that may be caused by the chemotherapy drugs used for the stem cell collection process are similar to what you would have experienced during your previous chemotherapy. Some people have very few side effects, while others have many.

Almost all side effects are short-term and will gradually disappear once the treatment stops. The main areas of your body that may be affected by chemotherapy are those where there is a high turnover of normal cells, such as the lining of your mouth and digestive system, your skin, hair and bone marrow. Detailed information on the side effects of individual chemotherapy drugs and chemotherapy combinations that will be used during the mobilisation process are available in separate booklets. The stem cell transplant nurse co-ordinator will provide you with these.

Following chemotherapy and G-CSF it is possible that your white count may be low for a few days. This means you are at greater risk of infection. If you feel unwell or have a fever above 38° you must call the hospital, as we may need to admit you and start some strong antibiotics. This does not happen very often but may occur, therefore it is important to contact your healthcare team if you are unwell. You may be able to have medicines to minimise some side effects.

What happens if my bone marrow does not mobilise any stem cells?

You may struggle to mobilise stem cells from your bone marrow and therefore we will be unable to collect these cells. This may be because of the type of treatment you have had or if you have had many courses of treatment in the past. Your doctor will discuss this with you before referring you for stem cell harvesting. It may be that you will need an additional attempt at stem cell mobilisation with a different chemotherapy or mobilising agent.

It is very important you do not miss a day of your G-CSF injections otherwise we may not be able to collect your stem cells.

Blood tests needed during the mobilisation

Blood tests will be taken on the predicted day of mobilisation to identify if there are enough stem cells in the peripheral bloodstream for collection and also to check you have recovered from the chemotherapy if you were given this as a mobilising agent. If you have not reached the target stem cell number in your blood, we may be able to use another drug called Plerixafor to help stimulate stem cell production.

Plerixafor

This is a drug for stem cell mobilisation. In addition to helping the bone marrow make new stem cells (together with the G-CSF) it also has a mechanism of action that helps any stem cells that may be ‘stuck’ in the bone marrow to be released into the blood stream where we can collect them and measure them. Plerixafor is given as a small injection under the skin (much like the G-CSF injection). It is usually very well tolerated, with the main side effects being:

- redness and tenderness at the injection site
- nausea
- diarrhoea
- loss of appetite.

If you do not have enough stem cells in your blood on your predicted day, the apheresis nurses will inform you if you are able to have Plerixafor as it depends on your blood counts and diagnosis. It may be better to start it that day or to wait and reschedule your mobilisation episode. This will be decided by the apheresis/transplant team in order to give you the best opportunity of mobilising and collecting stem cells. Your doctor may have already discussed and consented you for Plerixafor during your consultation.

Plerixafor has to be given at 5pm because of the peak activity of the drug and it must be given by the healthcare team in the hospital. You may wish to go home and return later if you live locally or plan to stay the day at the hospital if your travelling distance is too far.

The stem cell transplant nurse co-ordinator will provide you with a timetable of the process if we need to reschedule.

What actually happens during a stem cell collection?

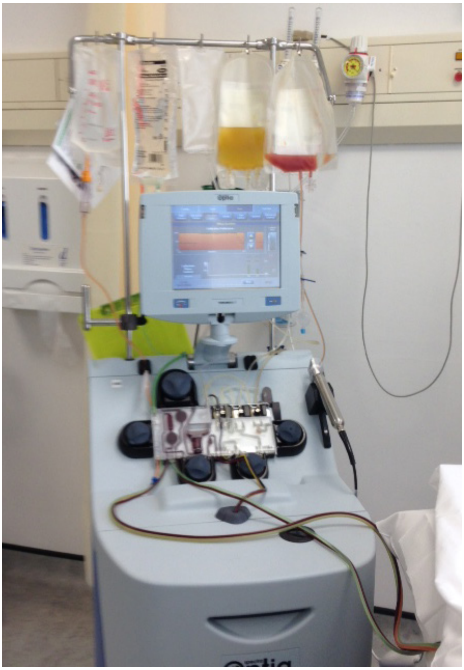
On the day of predicted stem cell mobilisation, we will ask you to attend The Royal Marsden Apheresis Unit at the agreed time (usually 8am). Please bring your remaining G-CSF injections with you.

If you are taking a blood thinner, do not take it the evening prior to collection. If you are on blood pressure medicines or diuretics, you may wish to abstain from these the morning of the planned procedure.

The procedure for collecting stem cells from the peripheral blood is known as ‘apheresis’ and is carried out as an outpatient procedure in one or two days, lasting about four to six hours on each day. There will be a nurse in attendance throughout the collection procedure.

The collection is done using a machine called a blood cell separator.

We will insert a needle into your arm to draw blood out into a sterile plastic circuit connected to the cell separator. The blood is mixed with a blood thinner while in the circuit to stop it from clotting. The blood is spun in a special machine (centrifuge) to separate the stem cells from the other parts of the whole blood. The stem cells are then collected into a sterile bag. The rest of the blood continues through the circuit and is returned by a needle into a vein in your other arm.



Blood cell separator

What can I do during the collection?

You will be lying or sitting on a reclining chair and can do anything calm (for example, read, write, watch television) during the procedure. You can eat breakfast on the morning of the procedure (calcium rich foods will be good such as milk, cheese, yoghurt) and you will be able to have refreshments once the collection has begun. You should use the toilet before the procedure starts. If you require the toilet during the procedure the nurse can help you with a bedpan or commode. You can have someone accompany you and stay with you during the stem cell collection.

What happens after the collection?

We may ask you to wait after the first collection for us to take a stem cell count so we can see whether enough stem cells have been collected for your transplant. If a second collection is necessary, you will receive another dose of G-CSF at the hospital prior to going home. We will then arrange for you to return to The Royal Marsden for another collection.

After the collections, you may feel tired for a short time. As a general rule, two to three days should be plenty to allow for recovery. These are only guidelines and you may find that you do not need any time off work, or that you need longer.

What are the risks and side effects of apheresis?

- bruising at the needle insertion sites
- feeling faint
- tingling around the mouth and face, fingers and toes
- a sense of ‘vibrating’, nausea, chills, and cramping can occur because of decreased calcium levels caused by the blood thinner. This is temporary and can be remedied effectively with calcium supplements.
- increased chance of bruising and bleeding if platelets (blood cells involved in clotting) are collected with the stem cells.

A blood test is taken after each collection to check the blood and platelet counts. The apheresis team will advise you to avoid strenuous activity, heavy lifting, and alcohol consumption if your platelets count has temporarily lowered. In very rare cases, you may need a platelet transfusion.

What happens if my peripheral veins are not suitable for the stem cell collection?

An important part of the pre-donation medical examination is to assess the suitability of your veins. We need good access to your veins to collect stem cells; this is usually possible using the veins in your arms. If these veins are not suitable, we will discuss with you the options of inserting a central catheter (a soft plastic tube inserted into a large vein in the chest) to collect the stem cells. This is an elective procedure requiring a day admission as the line is inserted under local anaesthetic in the operating theatre. It is estimated that 5 – 10 in 100 of patients need a central catheter.

We will discuss this with you in more detail if necessary and further information is available in The Royal Marsden booklet *Central venous access devices*.

In some cases your veins may not work well on the day of the procedure and we may have to insert a temporary intravenous line into your groin. This is rare and is performed by an anaesthetist under ultrasound guidance and local anaesthetic. However if you require a second day collection, you will have to stay in hospital overnight. The line will be removed by the nurse at the end of the procedure.

Risks are rare, but occasionally the central catheter does not function properly or becomes blocked. This is not a serious complication and can usually be corrected easily. Other very uncommon risks are local bleeding, infection and blood clot formation.

What happens after donation?

If we have collected enough stem cells for your transplant, the nurse co-ordinator will contact you to arrange an admission date. If we need to arrange for a further stem cell mobilisation attempt, we will give you a clinic appointment to discuss this with the transplant doctor.

The experience of donating should be as stress free as possible and we are happy to receive feedback on all aspects of donor care. Please do not hesitate to contact us if you experience any issues that may be related to the donation.

What happens to the cells after they have been collected?

The stem cells are taken to the stem cell transplant laboratory at The Royal Marsden where they are sampled. They then go to another laboratory to be counted so we know exactly how many have been collected and whether this is enough for your transplant. They are then very carefully frozen and stored in special containers within the stem cell laboratory until you need them. When you are admitted for your stem cell transplant, they will be defrosted on the day just before you need them and then infused into you in much the same way as a blood transfusion.

The consent to donate process

You will be asked to sign a form at the medical examination whereby you consent to donate stem cells for your own use. Copies of these consent forms are available on request for those wishing to read them before their medical appointment. Informed consent is approached as an ongoing process and not an isolated event. Even once you have signed the consent form you can still withdraw your consent. We encourage you to write down any questions you may have in the spaces provided at the back of this booklet to remind you to ask the doctors or nurses who will be caring for you. We will confirm consent on the day of your stem cell donation, before proceeding with the collection or harvest.

The law on consent

Since 2001, the Department of Health guidance on consent has required NHS Trusts to adopt a model consent policy, model forms and information leaflets with the aim of ensuring that good practice in seeking consent is in place throughout the NHS. You will be asked to consent to treatment/donation using these forms according to the Trust policy.

The HTA (Human Tissue Authority) is responsible for assessing all donations of stem cells from adults who lack capacity to consent and children who lack competence to consent. Potential donors and the person/s acting on the donor's behalf are interviewed by an Accredited Assessor (AA) who submits a report to the HTA.

Further information can be found from the following website:

www.hta.gov.uk

Contact details

Monday to Thursday (8am – 5pm)

Bud Flanagan Apheresis unit

Tel: 020 8661 4258

Stem cell transplant nurse co-ordinators

Tel: 020 8661 3785 and 020 8642 6011 ext 4091

After hours, weekends and bank holidays

Ask for the on-call doctor for haematology

Tel: 020 8642 6011

(switchboard will bleep the senior nurse on 017)

The Royal Marsden Macmillan Hotline: 020 8915 6899

You can ring the hotline 24 hours a day, 7 days a week.

Call us straight away if you are feeling unwell or are worried about the side effects of cancer treatments.

This service provides specialist advice and support to all Royal Marsden patients, as well as to their carers, and both hospital and community-based doctors and nurses caring for Royal Marsden patients.

Useful websites

The Anthony Nolan Trust: *www.anthonynolan.org*

World Marrow Donor Association: *www.wmda.info*

National Marrow Donor Program: *www.bethematch.org*

Macmillan Cancer Support: *www.macmillan.org.uk*

Glossary

Chemotherapy: Chemotherapy is the use of anti-cancer (cytotoxic) drugs to destroy cancer cells (including leukaemia and lymphoma). Chemotherapy may be used alone to treat some types of cancer. It may also be used with other types of treatment such as surgery, radiotherapy, hormonal therapy, biological therapies, or a combination of these.

Cytomegalovirus (CMV): CMV can be passed on by breathing in the droplets from the coughs and sneezes of an infected person. It can also be caught through having unprotected sex with a person who has the virus, or having donated organs or blood transfusions from someone with CMV. Once you have CMV, it remains in the body for life. If you have got a strong immune system, it will not have any effects, or may just have mild ones. But if your immune system becomes weak later in life, for example if you have chemotherapy, the virus can be activated.

Hepatitis B (HBV): HBV is a virus which spreads through the blood and bodily fluids of an infected person. The hepatitis B virus can go on to cause a chronic (long-term) illness, which follows an acute infection. This is very common in babies and young children, but it can also occur in adults. If you develop chronic hepatitis B, you may remain well, but you may pass on the virus because you are a carrier. Symptoms may come and go, or you may develop serious liver damage.

Hepatitis C (HCV): HCV is a blood-borne viral infection. Very rarely it can also be passed on through other body fluids, such as through having unprotected sex. Drug users sharing needles are particularly at high risk, but also anyone whose blood has come into contact with the blood of someone infected with hepatitis C. The virus is not transmitted through normal social contact, such as hugging, kissing, sharing kitchen utensils, or via a toilet seat. Approximately 20% of people will fight the infection and naturally clear it from their bodies within two to six months. Of the rest some will remain well, and never develop liver damage but many will develop mild to moderate liver damage (with or without symptoms). A further 20% will progress to cirrhosis (scarring of the liver) over a period of 20 to 30 years. Excessive drinking of alcohol is often associated with increased likelihood of progression to severe liver complications.

Human Immunodeficiency Virus (HIV): HIV is a sexually transmitted virus (STI) that attacks the body's immune system, which provides a natural defence system against disease and infection.

Human T cell lymphotropic virus (HTLV): HLTV is quite rare in the UK, with only an average of 50 new cases occurring each year.

Radiotherapy: Radiotherapy is the use of high energy x-rays and similar rays (such as electrons) to treat disease. Many people with cancer will have radiotherapy as part of their treatment. Radiotherapy works by destroying the cancer cells in the treated area. Although normal cells can also be damaged by the radiotherapy, they can usually repair themselves.

Syphilis: Syphilis is a bacterial infection that is typically passed through sexual contact. However, it can be passed on by intravenous drug use (injecting drugs directly into the vein), blood transfusions and from an infected mother to her unborn child. The latter is known as congenital syphilis.

References

This booklet is evidence based wherever the appropriate evidence is available, and represents an accumulation of expert opinion and professional interpretation.

Details of the references used in writing this booklet are available on request from:

The Royal Marsden Help Centre
Freephone: 0800 783 7176
Email: patientcentre@rmh.nhs.uk

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Should you require information in an alternative format, please contact The Royal Marsden Help Centre.

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