

Information on STEM CELL TRANSPLANTS

What is a Stem Cell Transplant?

A stem cell transplant is an infusion of stem cells following high-dose chemotherapy. The infused cells effectively rescue the patient from the toxic effects of the chemotherapy on the bone marrow. The infusion process is similar to a blood transfusion.

There are two types of stem cell transplants: autologous and allogeneic. In an autologous transplant, the patient's own stem cells are infused. In an allogeneic transplant, donor stem cells are infused.

The vast majority of stem cell transplants for myeloma are autologous.

This pamphlet focuses on autologous transplants.

When stem cell transplants were first developed, the stem cells were obtained from the patient's bone marrow; hence, the procedure was known as a bone marrow transplant. Stem cells are now collected from the patient's circulating (or peripheral) blood; hence, the procedure is now known as a peripheral blood stem cell transplant.

Myeloma Treatment

High dose chemotherapy (HDT) with an agent called Melphalan is one of the most effective therapies for myeloma. This procedure can be made safer and more effective by the use of blood stem cells, which are able to form all the elements of the blood.

Initial treatment for many myeloma patients often involves combinations of anti-myeloma agents to get

the patient to a remission. The level of response and outcome can be markedly improved by the use of HDT.

HDT is very effective at killing myeloma cells, but is also toxic to blood-forming stem cells in the bone marrow. If given alone without steroids it prevents blood cell production permanently, leading to inadequate numbers of red blood cells, white blood cells and platelets, each of which perform essential functions. Without adequate blood cell counts, patients experience multiple life-threatening complications.

- Red blood cells carry oxygen from the lungs throughout the body
- White blood cells fight infection
- Platelets form clots to control bleeding from injuries

Permanent blood cell suppression can be prevented by infusing healthy blood-forming stem cells collected from the patient's blood stream 24 hours after the HDT has been given (when it has been metabolized by the body).

The procedure consists of flushing stem cells out of the bone marrow into the peripheral blood from where they can be collected using a special machine. These healthy stem cells are collected and stored after the patient has responded to initial anti-myeloma agents. Then high doses of chemotherapy are administered to wipe out the remaining myeloma cells in the bone marrow and a subsequent infusion of the stored stem cells "rescues" the bone marrow and stimulates

production of normal, healthy cells. This regimen is very effective and can produce long-lasting response, with the capability of putting myeloma into complete remission.

Successes

The Myeloma Institute has successfully employed stem cell transplantation since the program's founding in 1989. We pioneered the use of two back-to-back transplant procedures, known as a Tandem Transplant. This approach has been an integral component of the Myeloma Institute's Total Therapy treatment regimen. Through the use of this procedure, survival rates have increased dramatically, resulting in significant cure rates.

The Myeloma Institute was the first to perform stem cell transplants on an outpatient basis and to demonstrate the safety of transplantation in elderly patients and those with renal failure.

The Myeloma Institute prefers doing transplantation on an outpatient basis unless medical factors necessitate hospitalization. The outpatient setting keeps patients in a comfortable, normal environment and reduces the risk of hospital borne infections.

Process

Quick overview

- 1) Induction: The patient is treated with induction chemotherapy to decrease the number of myeloma cells in the bone marrow.
- 2) Mobilization, Harvest & Collection: The patient is treated with a stem cell mobilizer injection to push stem cells out of the bone marrow into the circulating blood, from where they can be collected (harvested).
- 3) Storage: The harvested stem cells are frozen for use later on when they are needed. We collect enough stem cells for a number of stem cell transplants.
- 4) Conditioning & Stem Cell Infusion: The patient receives high-dose therapy (HDT), followed by infusion of thawed stem cells to restore normal blood cell production.
- 5) Recovery: Blood counts fall over 5 days in response to the HDT, but engraftment of the infused cells normally occurs by day 10-14.

Induction chemotherapy

Pre-transplant chemotherapy is known as induction treatment. The aim of induction treatment is to reduce the amount of myeloma in the bone marrow before stem cells are collected. Stem cells that are collected when the patient is in remission are less likely to be contaminated by myeloma cells. Courses of induction chemotherapy usually last for several months and are given in cycles. The number of cycles varies, depending on the individual's response to the treatment.

Side effects of induction treatment, including nausea, fatigue and anemia, can be managed so the patient has minimal discomfort and interruption to daily life.

Stem Cell Mobilization & Harvesting

Peripheral blood stem cells are extracted from circulating blood after the patient has been treated with a growth factor called Granulocyte Colony Stimulating Factor (G-CSF), either alone or with additional chemotherapy, to mobilize stem cells into the blood.

G-CSF stimulates the bone marrow to release stem cells into the blood. Chemotherapy causes a drop in blood cell counts, and when the blood counts come back up stem cells are released into the circulating blood. When the stem cell count in the circulating blood is high enough, the cells are collected through a process called apheresis and then processed and frozen until needed.

If patients receive chemotherapy, stem cell collection begins just as the blood counts start to recover. Since the time during which increased production of peripheral blood stem cells is limited, and because the first days of collection are the most important, patients must stay in Little Rock for frequent blood work assessments.

Patients for whom mobilization is not successful may be given injections of Mozobil, which works by disrupting the way stem cells adhere to the bone marrow. This results in the release of stem cells from the bone marrow and can improve mobilization and increase the number of stem cells harvested.

Side effects of mobilization

The most common side effects of mobilization with G-SCF are temporary general and bone aches, joint pain and fever, all of which can be treated with mild pain-killers. Common side effects of chemotherapy used for mobilization include nausea, loss of appetite, skin rash, general weakness and loss of hair.

Side effects of Mozobil may include nausea, diarrhea, dizziness, headache, joint pain and irritation at the injection site.

Stem Cell Collection

Peripheral blood stem cells are collected, or harvested, through a process called apheresis. A blood cell separator machine draws blood from the body, separates the different blood cells, draws off the stem cells and then returns the rest of the blood cells back to the patient. The machine operates a very rapid withdrawal and return of blood, necessitating a special catheter via a central venous line that is placed in the chest wall by interventional radiology or a surgeon prior to the start of the collection process.

The number of apheresis procedures for sufficient collection differs for each person. Two or three collections over consecutive days are usually required to collect a sufficient quantity of cells for most patients. Each procedure may last up to four hours.

A marker on the cell surface called CD34 is used to determine the quantity and quality of stem cells that have been collected.

The minimum number of stem cells needed for a successful transplant is roughly two million per kilogram of body weight. However, we collect enough stem cells for multiple transplants.

Stem Cell Storage

In the Cell Therapy Processing Lab a cryoprotective agent is added to the collected stem cells. This prevents water in the cells from forming ice crystals, which would permanently damage the stem cells during the freezing process.

Stem cells are placed in special bags and then stored in liquid nitrogen. Frozen stem cells can be stored indefinitely.

UAMS has a specialized apheresis unit and processing lab with tight controls and thorough tracking and monitoring. The units are accredited by the Foundation for the Accreditation of Cellular Therapy (FACT). FACT is an accrediting organization that addresses all quality aspects of cellular therapy treatments: clinical care, donor management, cell collection, cell processing, cell storage and banking, cell transportation, cell administration, cell selection, and cell release. FACT-accredited organizations voluntarily seek and maintain their accreditation through a rigorous process.

Transplantation

In order to prepare the body for transplant, the patient receives high-dose therapy, usually Melphalan. The main function of the high-dose therapy is to destroy the cancerous myeloma cells.

Infusion of the stem cells typically takes place about 24 hours after completion of the conditioning chemotherapy regimen. The actual infusion takes about 45 minutes. If the volume of cells to be infused is especially large, the infusion can be spread over two days.

After the stem cells are infused there is a waiting period of about 5 days, during which the counts of white cells, red cells and platelets will drop. The counts return to normal limits usually starting about 10 days after the stem cells were infused. The process of the transplanted cells "taking" and beginning to grow in the bone marrow is referred to as engraftment. The time from transplant to engraftment is usually between 10 and 16 days. During this time period, when blood counts are low, patients usually feel their worst and are at risk for infection. Transfusions of red blood cells and platelets are given, if needed, to support the blood counts.

Side effects of Stem Cell Transplantation

The Myeloma Institute places an emphasis on supportive care throughout the entire treatment and recovery process. We do everything possible to minimize side effects and discomfort.

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This information about Stem Cell Transplant and other patient education materials are available at www.myeloma.uams.edu

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