have occurred, they are very uncommon and very unlikely to occur.

Collection:

Occasionally with blood stem cell collections, there may be a small, temporary decrease in the blood count after the apheresis sessions. These decreases should not cause symptoms nor be noticeable to you. Also, some patients experience transient tingling sensations around the mouth or in the fingers and toes during the procedure. This effect is due to the anticoagulant (blood thinner) used during the procedure, and it responds to a slowing of the procedure or the use of calcium-containing medications.

If a catheter is used to collect blood during the apheresis, infection can occur. This risk is reduced by good hygiene and care of the catheter. Blood clots also can form around the catheter, and this risk will be minimized by flushing the catheter after each use with blood thinners, or by rinsing the catheter with medicines that quickly dissolve blood clots.

In patients who undergo apheresis without a catheter, there may be local discomfort or bruising where two needles have been placed in the arm veins. Local infections in the area of the venipuncture are extremely rare after apheresis. This risk is minimized by sterile cleansing of the skin before inserting the needles. Occasionally, a patient will experience temporary periods of low blood pressure during apheresis, but this problem can be corrected quickly with infusions of saline (salt water).

There is no risk of acquiring AIDS during an apheresis procedure since blood drawn and returned is your own and is processed with sterile, disposable equipment at all times during the procedure.

Benefits

The cells collected may benefit you in the course of treatment. However, there is no guarantee that the collection will be adequate to either cure or lessen the severity of you disease or condition.

Conditions of storage and disposal

It is possible that unused cells from those donated for use at NCCCR, may be placed in frozen storage. Because of this possibility, you will be asked to sign “Consent for the Testing, Storage and Discarding of Stem Cells or Lymphocytes” by NCCCR. This agreement will detail the terms for the storage, transfer, and disposal of any unused cells. You will be given a copy of this signed agreement for your records.

After Collection

You will be advised to have someone accompany you home after your outpatient apheresis. After the procedure, you will be given a contact number to call if you feel ill.

Bone Marrow Transplant Unit

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Patient and Family Education

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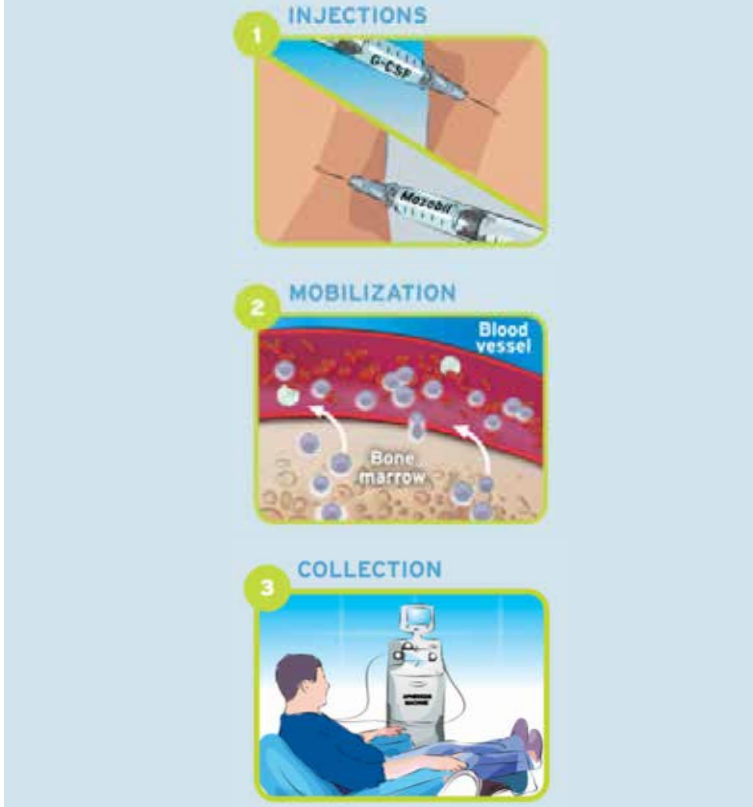
18-0293

The priming, mobilization and collection of peripheral blood stem cells



المركز الوطني لعلاج وأبحاث السرطان
National Center for Cancer Care & Research

The priming, mobilization and collection of peripheral blood stem cells

The procedure will be carried out under the supervision of physician(s) in the Hematology Department, but others working with them may be designated to assist or act for them.

General description of the procedure

This consent will cover the priming, mobilization and collection of peripheral blood stem cells for use in an autologous stem cell transplant. This process may include the utilization of a chemotherapeutic agent.

Priming and mobilization

The first step in the process is "priming". The term blood cell "priming" refers to ways to increase the number of stem cells mobilized and subsequently collected. Before priming, a soft plastic tube can be used to withdraw or introduce fluids (called a catheter). This may be inserted into a large vein in your upper chest using a sterile technique by a surgeon. This tube could also be inserted into a large vein in the femoral region. Next, daily injections under the skin of a blood growth factor called granulocyte colony stimulating factor (G-CSF) will be given. G-CSF could be preceded by standard chemotherapy given intravenously. This priming should greatly increase the number of stem cells that can be collected from the blood.

The chemotherapy used in this procedure will be discussed and explained to you by your treating physician.

Collection of cells:

The method of collecting blood stem cells is called apheresis, a procedure that involves processing your blood using a machine to remove some stem cells and return other blood cells. These machines have been widely used to collect certain types of blood cells from normal people for subsequent use in transfusions. The priming and apheresis procedures are usually done on an outpatient basis. The catheter might also be used to remove blood with the apheresis machine. The catheter placement, blood stem cell priming and collection by apheresis are standard (non-research) procedures. The apheresis will be done at the National Center for Cancer Care and Research (NCCCR) - Hamad Medical Corporation, Doha-Qatar.

Tests performed and the right to review the test results

You will have a complete medical history and physical exam taken as well as laboratory studies, electrocardiograms, pulmonary function tests, echocardiograms and x-rays. You be screened for several blood borne diseases including HIV, the virus that causes AIDS and any test result which may have an implication for you will be shared with you. You will also have the right to review all the test results. None of these test results will be shared with anyone else without your consent.

General risks with this procedure:

Common side-effects include bruising or bleeding, anemia (low number of red blood cells), feeling sick (nausea) and being sick (vomiting). This treatment can also cause tiredness, hair loss, and loss of appetite, sore mouth and mouth ulcers. The treatment can cause either diarrhea or constipation. There may be an increased risk of tumor-lysis syndrome in the presence of high tumor burden (high number of cancer cells present in the body). Precautions will be taken to minimize the risk of complications with preventative supplementary medicines. Reduced resistance to infection is one of the possible side effects.

Other potential side-effects with the anti-sickness medication may include: constipation, headaches, indigestion, difficulty sleeping and agitation. Some chemotherapy drugs can damage women's ovaries and men's sperm, with a risk of infertility and early menopause in women.

Some chemotherapy drugs may lead to many risks associated with an abnormal pregnancy. This is an issue for both men and women. It is recommended not to become pregnant / not to get a partner pregnant during the period of treatment.

Granulocyte-colony stimulating factor (G-CSF):

The side effects of G-CSF injections are usually mild and short-lived, and may include low grade fever, mild nausea, abdominal cramping, headache, bone and joint pain, muscle aches, and rash. Rarely, allergic reactions, including wheezing and low blood pressure, may occur. Other side effects that are very rare but have occurred include lung or hearing problems, fluid retention, ruptures of the spleen, or blood clots. Though severe side effects