

CLINICAL TRIAL INFORMATION SHEET - BMT CTN PROTOCOL

A Trial of Tandem Autologous Stem Cell Transplants +/- Post Second Autologous Transplant Maintenance Therapy Versus Single Autologous Stem Cell Transplant Followed by Matched Sibling Non-myeloablative Allogeneic Stem Cell Transplant for Patient with Multiple Myeloma

WHY IS THIS STUDY IMPORTANT?

- ◆ Information from this clinical trial will help doctors make better treatment choices for future patients with multiple myeloma.

WHO MAY JOIN?

Patients who join this clinical trial must:

- ◆ Be under the age of 70.
- ◆ Have multiple myeloma and have received at least 3 months of therapy.
- ◆ Have enough stem cells for an autologous transplant.

HOW MANY PEOPLE WILL JOIN?

- ◆ 500 patients at about 35 medical centers will join the study over three years.

WHO PROVIDES OVERSIGHT?

- ◆ The National Heart, Lung and Blood Institute and the National Cancer Institute with the Blood and Marrow Transplant Clinical Trials Network and its participating clinical sites.

TYPES OF TRANSPLANTS USED IN THIS STUDY:

- ◆ An autologous transplant uses blood stem cells from the patient.
- ◆ An allogeneic transplant uses blood stem cells collected from a brother or sister who is a tissue match with the patient.

WHAT CAN YOU EXPECT?

- ◆ First, all patients in the study will receive an autologous transplant.
 - ✓ If you have a sibling donor, you will receive an allogeneic transplant after the autologous transplant.
 - ✓ If you do not have a sibling donor, you will receive a second autologous transplant and assigned by chance (like the flip of a coin) to either maintenance therapy or observation for one year.
- ◆ You will have blood and medical tests on a scheduled basis.
- ◆ You will be asked to complete two questionnaires about your physical and emotional health before each transplant, then at 6 months, 1 year, 2 years, and 3 years after your second transplant.
 - ✓ You can decide not to do the interview and still be on the study.
 - ✓ You can choose to skip any question you wish.
- ◆ You will be asked to give small blood samples for research.
 - ✓ You can decide not to give these blood samples and still be on the study.
- ◆ You may or may not benefit from being in this study. Your taking part may help patients in the future.

HOW LONG DOES THE STUDY LAST?

- ◆ You will be in the study for about 3 and a half years from the start of your first transplant.
- ◆ Your doctors may stop your participation in the study at any time if they are worried about your safety.
- ◆ Being in the study is your choice. If you meet the requirements and wish to be in the clinical trial, you will sign the consent form. You can always decide to leave the study at any time.

WHO WILL PAY COSTS

- ◆ You or your insurance company will pay the bills for your medical treatment
- ◆ You will not be charged for research tests

WHERE TO GET MORE INFORMATION?

- ◆ Office of Patient Advocacy at the National Marrow Donor Program - call 1-888-999-6743
- ◆ NIH web site: <http://www.nih.gov/>
- ◆ Center Name _____
- ◆ Contact person _____