



## BMT CTN 0403 Study Summary Sheet

Informed Consent for a clinical trial has two parts. The first part is a process to provide you with information you need to make an educated decision about participating in the trial. You will be given this document, a summary of the study, and a copy of the informed consent document. You will read through this information with a doctor or nurse and be able to ask questions and tell them if you have any concerns. You will also be given time to talk about this information with your family. If you choose to take part in the study, you will sign the informed consent document.

The second part of informed consent is ongoing. It means that doctors and nurses will continue to give you any important information about the study or your condition. You will always have the information you need to make an informed decision.

### **What is the goal of this study?**

Idiopathic Pneumonia Syndrome (IPS) is a serious condition that can occur after a stem cell transplant. It means you have fluid, congestion, or swelling in your lungs. Unlike regular pneumonia, though, there are no germs or infection in the lungs. Steroids are the most common treatment for IPS. The goal of this study is to find out if giving etanercept plus steroids helps patients more than steroids alone. Etanercept is approved by the Food and Drug Administration (FDA) for other conditions.

### **Am I eligible for the study?**

You may be eligible for the study if you are at least 18 years in age or older, you received a stem cell transplant in the last 3 months, and you have IPS. Your doctor will do tests to make sure that you are eligible. You will have to sign an informed consent document.

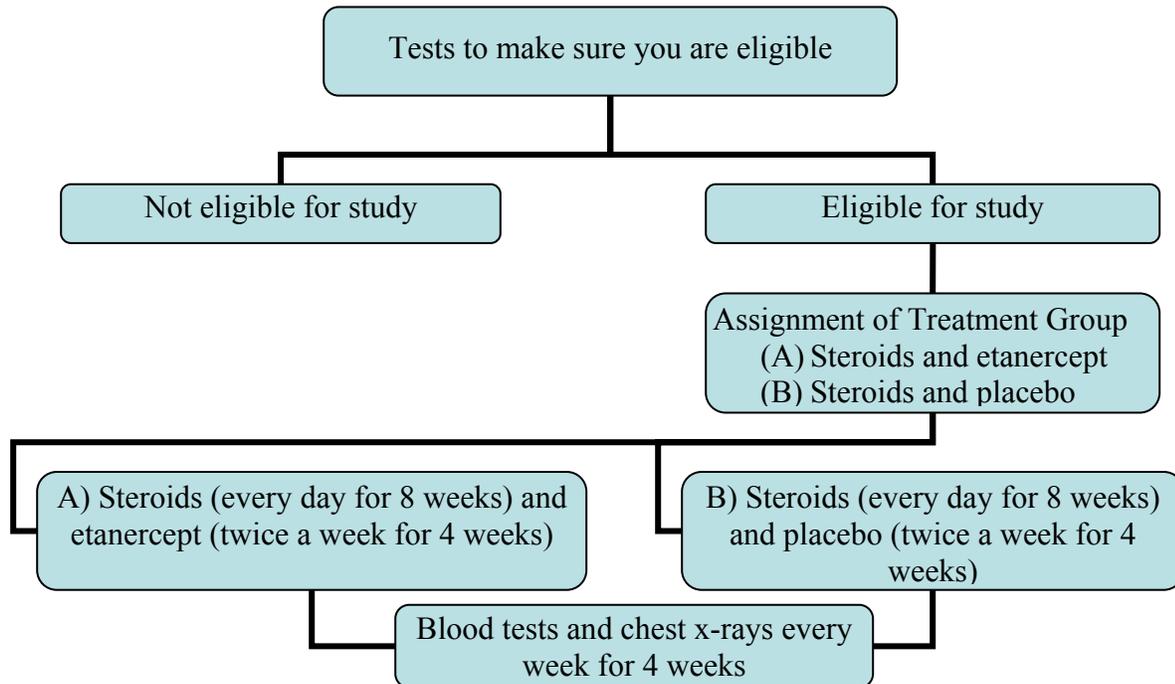
### **What treatment will I get?**

You will get steroids, the standard treatment for IPS, for approximately 4- 8 weeks (2 months). You will also get a total of eight doses of etanercept (or placebo) over a 4-week period (1 month). Placebo is a treatment that looks like the drug being tested, but has no effect on your body. The first dose of etanercept (or placebo) will be given intravenously (IV) and the rest will be given as injections. In addition, you will have blood tests and chest x-rays every week for 4 weeks.

### **Will I get to choose my treatment?**

No. All patients will be treated with steroids, but you will not be able to choose if you will receive etanercept or placebo. A computer will determine which treatment you get, much like flipping a coin. You will have an equal chance of getting either treatment. Neither you nor your doctor will know which treatment you are receiving.

**Your treatment plan will look something like this:**



**How long will I be in the study?**

You will be treated for 8 weeks (2 months). With follow-up, your participation will last for 3 years.

**Can I leave the study?**

If you choose to leave the study, it will not affect your medical care. You will still be able to receive treatment at our hospital and you will not lose any of your regular benefits. If you decide to leave the study, make sure to talk to your doctor about the safest way to do this.

**How much does it cost to be in the study?**

There are two types of costs in a clinical trial: research costs and patient care costs. Research costs include the cost of the etanercept or placebo and the tests or procedures that are done only for research. You will not have to pay for the research costs. Many insurance companies will pay for some or all of the patient care costs. Talk to your insurance company to find out for sure.

You will not be paid to participate in this study.

**What happens if I don't participate in the study?**

It is your choice to participate in the study. If you do not, it will not affect your medical care. You will still be able to receive treatment at our hospital and you will not lose any of your regular benefits.

**Will my medical information be kept private?**

Your participation in this study will be kept private and confidential. The results may be published in a scientific journal, but you will not be identified by name.